To: Title VI Complaints[Title_VI_Complaints@epa.gov]; Daria Neal (daria.neal@usdoj.gov)[daria.neal@usdoj.gov]; Joe Leonard Jr. Ph. D (program.intake@usda.gov)[program.intake@usda.gov]
Cc: Paul Achitoff[achitoff@earthjustice.org]; Kylie Wager[kwager@earthjustice.org]; Mccarthy, Gina[McCarthy.Gina@epa.gov]; Tom Vilsack (tom.vilsack@usda.gov)[tom.vilsack@usda.gov]; Strauss, Alexis[Strauss.Alexis@epa.gov]
From: Julie Parks
Sent: Wed 9/14/2016 10:09:31 PM
Subject: Complaint Under Title VI of the Civil Rights Act of 1964, 42 U.S.C. § 2000d, 40 C.F.R. Part 7, and 7 C.F.R. Part 15
Title VI Complaint and Exhibits.pdf

Dear Acting Director Dorka, Assistant Secretary Leonard, and Deputy Chief Neal:

On behalf of Paul Achitoff and Kylie Wager of Earthjustice, please find The Moms On a Mission Hui and Pōʻai Wai Ola/West Kauaʻi Watershed Alliance's Title VI complaint and exhibits, attached.

Sincerely,

Julie Parks

Litigation Assistant

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September 14, 2016

By email and certified mail

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Re: Complaint Under Title VI of the Civil Rights Act of 1964, 42 U.S.C. § 2000d, 40 C.F.R. Part 7, and 7 C.F.R. Part 15

Dear Acting Director Dorka, Assistant Secretary Leonard, and Deputy Chief Neal:

The Moms On a Mission Hui (The MOM Hui) and Pōʻai Wai Ola/West Kauaʻi Watershed Alliance (Pōʻai Wai Ola), collectively, "community groups," by and through their counsel Earthjustice, call upon the U.S. Environmental Protection Agency (EPA) Office of Civil Rights (OCR) and the U.S. Department of Agriculture (USDA) Office of the Assistant Secretary for Civil Rights (OASCR) to investigate and ensure the policies, programs, and activities of the Hawaiʻi Department of Agriculture (HDOA) and the Hawaiʻi Agribusiness Development Corporation (ADC) comply with Title VI of the Civil Rights Act of 1964 and EPA and USDA's implementing regulations, 50 C.F.R. Part 7 and 7 C.F.R. Part 15, respectively.

HDOA and ADC are failing to comply with Title VI and implementing regulations because their actions and failures to act have an unjustified disproportionate and adverse effect on Native Hawaiians in West Kauaʻi and on Molokaʻi. Community groups request that OCR and OASCR promptly and thoroughly investigate the allegations set forth in this complaint and

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take all actions necessary to ensure that the agencies comply fully with the law and provide equal protection for the people of Hawai'i.

I. PARTIES

A. Complainants

The MOM Hui is a grassroots group of forward-thinking mothers who advocate for protecting the health, safety, and well-being of all children, present and future. The MOM Hui was created on Moloka'i and has since expanded to Kaua'i, O'ahu, and Maui. The MOM Hui's primary concerns are food and health, with a specific focus on seed production and experimentation, and the correlative increases in pesticide use. The MOM Hui's members and their children are directly affected by heavy pesticide application to seed crops on Moloka'i. The MOM Hui also engages in educational and fundraising activities to promote healthy living and bring awareness to genetically engineered seed companies' impact on communities. The MOM Hui campaigned for the passage of a moratorium on genetically engineered crop production in Maui County and Kaua'i County and is involved in a lawsuit defending the moratorium. *See* Declaration of Mercy Ritte ¶ 2-8 (attached as Ex. 1) (Ritte decl.); Declaration of Malia Chun ¶ 3-8 (attached as Ex. 2) (Chun decl.).

Pō'ai Wai Ola is a community-based organization established by Waimea watershed residents, farmers, and users, including Native Hawaiian cultural practitioners, to address water issues affecting West Kaua'i. Pō'ai Wai Ola members live, work, recreate, and practice their culture near large-scale pesticide spraying operations, and rely on, use, or seek to use the Waimea watershed and surrounding areas for a host of public trust uses including, but not limited to, fishing, agriculture, recreation, research and education, aesthetic enjoyment, spiritual practices, and the exercise of Native Hawaiian cultural rights and values. In a separate proceeding involving ADC and the Kekaha Agricultural Association's diversion of the Waimea River and its headwaters, Pō'ai Wai Ola has petitioned the Hawai'i Commission on Water Resource Management to restore these waters and cease water waste.

B. Recipients

HDOA is an agency of the State of Hawai'i charged with implementing and enforcing federal and state pesticides laws, among other responsibilities. Haw. Rev. Stat. (H.R.S.) § 26-16. HDOA's duties include licensing pesticides, *id.* pt. II, regulating pesticide use, *id.* pt. III, and investigating and resolving pesticide use complaints, Haw. Admin. R. (H.A.R.) § 4-1-37.

ADC is a state agency placed within HDOA, *id.* § 163D-3, charged with "mak[ing] optimal use of agricultural assets for the economic, environmental, and social benefit of the people of Hawaii," *id.* § 163D-1. ADC manages state agricultural lands, including approximately 12,500 acres on the Mānā Plain in West Kaua'i. *Id.* § 163D-4. ADC also operates a 40-mile drainage ditch system that runs through these lands and populated areas before draining into the ocean.

II. JURISDICTION

Title VI of the Civil Rights Act of 1964 provides that "[n]o person in the United States shall, on the ground of race, color, or national origin, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance." 42 U.S.C. § 2000d. As explained below, both HDOA and ADC are a "program or activity" covered by Title VI and receive federal assistance from EPA and USDA. This complaint is timely and satisfies all other jurisdictional requirements.

A. HDOA and ADC are Programs or Activities Covered by Title VI.

A "program or activity" includes "all of the operations of . . . a department, agency, special purpose district, or other instrumentality of a State or of a local government . . . any part of which is extended federal financial assistance." 42 U.S.C. § 2000d-4a. If any part of an entity receives federal funds, the whole entity is covered by Title VI. *Ass'n of Mex.-Am. Educ. v. California*, 195 F.3d 465, 474-75 (9th Cir. 1999), *rev'd in part on other grounds*, 231 F.3d 572 (9th Cir. 2000) (en banc).

HDOA is a department, agency, and instrumentality of the State of Hawai'i, H.R.S. § 26-16, and ADC is an agency and instrumentality of the state placed within HDOA, *id.* § 163D-3. Therefore, both HDOA and ADC's operations must comply with Title VI.

B. HDOA and ADC Receive EPA and USDA Assistance.

EPA and USDA regulations define "recipient" to include any instrumentality of a state or state agency to which "Federal financial assistance is extended, directly or through another recipient." 40 C.F.R. § 7.25; 7 C.F.R. § 15.2. As of August 15, 2016, EPA and USDA had awarded HDOA $783,290 in federal funds for the fiscal year 2016, and more than $20.2 million in federal funds since 2008.[1]

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[1] *See* USASpending.gov, https://www.usaspending.gov/transparency/Pages/RecipientProfile.aspx?DUNSNumber=809935257 (last visited Aug. 15, 2016) (showing EPA and USDA awards to HDOA (DUNS No. 809935257) for the years 2008 to the present); USASpending.gov, https://www.usaspending.gov/transparency/Pages/RecipientProfile.aspx?DUNSNumber=809935267&FiscalYear=2009 (last visited Aug. 15, 2016) (showing USDA awards to HDOA (DUNS No. 809935267) for the year 2009).

Tbl. 1. EPA and USDA Funding to HDOA

Year	EPA Funding	USDA Funding	Combined Total
2016	$513,450	$269,840	$783,290
2015	$184,213	$1,071,755	$1,255,968
2014	$375,325	$1,851,810	$2,227,135
2013	$397,925	$799,752	$1,197,677
2012	$258,325	$1,132,440	$1,390,765
2011	$308,125	$3,066,353	$3,374,478
2010	$414,125	$3,308,664	$3,722,789
2009	$349,725	$4,564,558	$4,914,283
2008	$308,125	$1,108,412	$1,416,537
Total	**$2,863,213**	**$16,375,569**	**$20,282,922**

C. The Complaint Is Timely.

EPA and USDA regulations generally require Title VI complaints to be filed within 180 calendar days of the alleged discriminatory act, but OCR and OASCR may waive these time limits. 40 C.F.R. § 7.120(b)(2); 7 C.F.R. § 15.6. In addition, OCR and OASCR have ongoing authority to review recipients' programs and activities for Title VI compliance. 40 C.F.R. § 7.115(a); 7 C.F.R. § 15.5(a). This complaint is timely because the discriminatory acts described herein are ongoing or within OCR and OASCR's investigatory authorities.

D. The Complaint Meets Other Jurisdictional Criteria.

This complaint satisfies all other jurisdictional requirements because it is in writing, describes the alleged discriminatory acts and is filed by an authorized representative with OCR and OASCR. 40 C.F.R. § 7.120; 7 C.F.R. § 15.6.

III. FACTUAL BACKGROUND

For centuries, the Native Hawaiian food system was rooted in the ahupua'a land management system, which organized natural resource use and access around land divisions that generally followed watershed boundaries from mauka (inland) to makai (sea). This system allowed optimal use of resources and ecosystem services over short distances, and many generations to survive and thrive.

Captain Cook's arrival to Hawai'i in 1778 ushered in a new era of agriculture focused on pesticide-intensive plantation crops for export, such as sugar and pineapple. This use depleted the soil, polluted water sources, and contributed to the decline of Hawai'i's food self-sufficiency.

As the plantation era declined in Hawai'i, seed crops grown for breeding rather than food increased. In 1966, seed firms planted 5 acres of test corn on Moloka'i, and by 1969, they had expanded winter seed corn operations to about 500 acres on Moloka'i, Maui, and Kaua'i. In the 1990s, the industry transitioned to genetically engineered crops, which now comprise the vast majority of seed crops in Hawai'i. Today, there are approximately 23,728 acres of genetically engineered seed crops on the islands of Kaua'i, Moloka'i, Maui, and O'ahu.

Hawai'i's seed corn cultivation is particularly chemical-intensive because corn requires more agrochemicals than other crops, seed corn requires still more chemical treatment because it is more susceptible to environmental stress and pests, and Hawai'i soils are not well-suited for corn to begin with. Moreover, many varieties of seed corn are now being developed specifically to resist the effects of particular pesticides, which are applied to these varieties during testing and production. Thus, it is no surprise that "there are likely an average of 30 or more spray operations most days of the year on Kaua'i."[2]

Although chemical and pesticide use poses health risks to communities throughout Hawai'i, seed operations are particularly pesticide-intensive, and are largely concentrated in West Kaua'i and Moloka'i, which have proportionately larger Native Hawaiian populations. For example, West Side communities from Kekaha to Hanapepe have among the greatest proportions of Native Hawaiians on the island, and the lion's share of Kaua'i's seed production. Moloka'i—where 2,342 acres of seed crops grow right in the center of the island—has more than three times the statewide percentage of Native Hawaiians and more than four times the statewide percentage of pure Native Hawaiians.

Pesticide companies have thus far successfully fought a county ordinance designed to require more transparency and protective measures for pesticide use. Regardless of this ordinance, HDOA and ADC have affirmative duties to ensure their programs and activities involving pesticides do not have discriminatory effects on people of color, including Native Hawaiians. HDOA and ADC are failing to fulfill these duties.

IV. LEGAL FRAMEWORK

Title VI of the Civil Rights Act of 1964 prohibits recipients of federal funds from discriminating against individuals on the basis of race, color, or national origin. 42 U.S.C. § 2000d. Title VI directs federal agencies granting federal assistance to issue regulations to achieve the statutory objectives. *Id.* § 2000d-1.

Acceptance of EPA or USDA assistance creates an obligation to comply with the agencies' respective Title VI regulations. 40 C.F.R. § 7.80(a)(1); 7 C.F.R. § 15.4(a)(1). EPA and

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[2] Hawai'i Center for Food Safety, Pesticides in Paradise, Hawai'i's Health & Environment at Risk (May 2015) at 30 (CFS Report).

USDA's Title VI regulations contain a general prohibition against discrimination, 40 C.F.R. § 7.30, 7 C.F.R. § 15.3(a), as well as more specific prohibitions, 40 C.F.R. § 7.35, 7 C.F.R. § 15.3(b). These regulations prohibit programs or activities that have either a discriminatory purpose or a discriminatory effect.

Under EPA regulations:

> (b) *A recipient shall not use criteria or methods of administering its program or activity which have the effect of subjecting individuals to discrimination* because of their race, color, national origin, or sex, or have the effect of defeating or substantially impairing accomplishment of the objectives of the program or activity with respect to individuals of a particular race, color, national origin, or sex.
>
> (c) *A recipient shall not choose a site or location of a facility that has the purpose or effect of* excluding individuals from, denying them the benefits of, or *subjecting them to discrimination* under any program or activity to which this part applies on the grounds of race, color, or national origin or sex; or with the purpose or effect of defeating or substantially impairing the accomplishment of the objectives of this subpart.

40 C.F.R. § 7.35 (emphases added).

USDA's regulations provide:

> (2) *A recipient, in determining the types of services, financial aid, or other benefits, or facilities which will be provided* under any such program, or the class of individuals to whom, or the situations in which, such services, financial aid, other benefits, or facilities will be provided under any such program or the class of individuals to be afforded an opportunity to participate in any such program, *may not, directly or through contractual or other arrangements, utilize criteria or methods of administration which have the effect of subjecting individuals to discrimination* because of their race, color, or national origin, or have the effect of defeating or substantially impairing accomplishment of the objectives of the program as respects individuals of a particular race, color, or national origin.
>
> (3) *In determining the site or location of facilities, an applicant or recipient may not make selections with the purpose or effect of excluding individuals from, denying them the benefits of, or subjecting them to discrimination* under any of its programs or activities to which the regulations in this part apply, on the grounds of race, color, or national origin; or with the purpose or effect of defeating or substantially impairing the accomplishment of the objectives of the Act and the regulations in this part.

7 C.F.R. § 15.3 (emphases added).

V. DISCRIMINATORY ACTS

HDOA and ADC's discriminatory actions and failures to act include both HDOA and ADC's lack of a Title VI program; HDOA's failure to limit pesticide registration; HDOA's failure to require or implement protective buffer zones between pesticide use and communities; HDOA's failure to adequately enforce federal and state pesticide laws; ADC's leasing or licensing of lands without protecting communities from pesticides; and ADC's refusal to obtain a permit under the Clean Water Act for its drainage ditch system.

A. HDOA and ADC Lack Title VI Programs.

HDOA and ADC are violating Title VI because both agencies lack a Title VI compliance program. Their acceptance of federal assistance created an obligation to implement a Title VI compliance program:

> In accepting this assistance agreement, the recipient acknowledges it has an *affirmative obligation to implement effective Title VI compliance programs and ensure that its actions do not involve discriminatory treatment and do not have discriminatory effects even when facially neutral*. The recipient must be prepared to demonstrate to EPA that such compliance programs exist and are being implemented or to otherwise demonstrate how it is meeting its Title VI obligations.[3]

On March 23, 2016, Earthjustice submitted public records requests to HDOA and ADC seeking materials documenting any Title VI compliance program they may have.[4] On March 30, 2016, ADC responded to the public records request as follows:

> [ADC] *does not have any Title VI compliance programs*, and therefore has no document responsive to this request.[5]

[3] EPA General Terms and Conditions Effective March 29, 2016, ¶ 26.c.iii (emphasis added).

[4] Request to Access a Government Record from Paul Achitoff, Earthjustice, to State of Haw. Dep't of Agric., Mar. 23, 2016 (attached as Ex. 3); Request to Access a Government Record from Paul Achitoff, Earthjustice, to State of Haw. Agribus. Dev. Corp., Mar. 23, 2016 (attached as Ex. 4).

[5] Letter from James Nakatani, State of Haw. Agribus. Dev. Corp. to Paul Achitoff, Earthjustice, Mar. 30, 2016 (emphasis added) (attached as Ex. 5).

On April 27, 2016, HDOA responded to the request by acknowledging it "does not have a document specifically described as HDOA Title VI program."[6] Instead, it provided its "Discrimination/Harassment-Free Workplace Policy"[7] and its "Limited English Proficiency Plan,"[8] and mentioned a "standard contract provision requiring all contractors to comply with local, State, and federal laws or with the standard grant provision similarly requiring compliance with all federal laws."[9] These standard documents do not establish a Title VI program.

Because HDOA and ADC lack a Title VI program to ensure that the agencies' actions "do not involve discriminatory treatment and do not have discriminatory effects"[10] on communities of color, including Native Hawaiians, the agencies are violating Title VI and the terms of the agencies' funding.

B. HDOA Has Failed to Limit Registration of Harmful Pesticides.

HDOA is violating Title VI by failing to place protective limits on pesticide registration, and thereby discriminating against Native Hawaiians. Under the Hawai'i Pesticides Law, H.R.S. Chapter 149A, "[a]ny pesticide which is received, used, sold, offered for sale, or distributed within this State shall be licensed by the board [of agriculture]." H.R.S. § 149A-13. HDOA may refuse to license a pesticide if the proposed use would "result in unreasonable adverse effects on the environment." *Id.* § 149A-14(a). To protect health and the environment, HDOA may cancel a pesticide license after determining that continued use of the pesticide would "result in unreasonable adverse effects on the environment." *Id.* § 149A-14(b). While cancellation proceedings are pending, HDOA may suspend a pesticide license "to prevent an imminent hazard." *Id.* § 149A-14(c). Pesticide licenses are otherwise valid for three years. H.A.R. § 4-66-35(b).

HDOA has failed to place *any* limits on pesticide registration, despite discriminatory adverse effects on health and the environment. For example, on January 20, 2016, 10 fieldworkers for Syngenta Seeds, Inc. were exposed to pesticides and taken to Kaua'i Veterans

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[6] Email from Bryan Yee, State of Haw. Dep't of Agric, to Paul Achitoff, Earthjustice, Apr. 27, 2016 (attached as Ex. 6).

[7] State of Haw. Dep't of Human Res. Dev., Policies and Procedures, Discrimination/Harassment-Free Workplace Policy, Policy No. 601.001, eff. Oct. 15, 2013 (attached as Ex. 7).

[8] State of Haw. Dep't of Agric., Department of Agriculture Limited English Proficiency Plan, July 1, 2013 (attached as Ex. 8).

[9] Email from Bryan Yee, State of Haw. Dep't of Agric, to Paul Achitoff, Earthjustice, Apr. 27, 2016.

[10] EPA General Terms and Conditions Effective March 29, 2016, ¶ 26.c.iii.

Memorial Hospital.[11] The fieldworkers walked onto a field that had been sprayed with the neurotoxic organophosphate pesticide chlorpyrifos.[12] In 2006 and 2008, children and schoolteachers of Waimea Canyon Middle School, near more of Syngenta's agricultural fields, were taken to the hospital suffering symptoms of pesticide exposure.[13] During the 2006 incident, 60 children and at least 2 teachers experienced headache, dizziness, nausea, or vomiting.[14] At least 10 children were treated at an emergency room, several were put on a nebulizer to relieve respiratory distress, and one was given an anti-vomiting medication intravenously. Air samples collected at the school—an investigation not undertaken until years after these events—revealed the presence of chlorpyrifos, metolachlor and bifenthrin.[15] Despite these incidents, HDOA has not limited registration of dangerous pesticides such as chlorpyrifos in any way, and therefore is violating Title VI.

C. HDOA Has Failed to Require Protective Buffer Zones Between Pesticide Use and Communities.

HDOA is violating Title VI by failing to require, implement, and ensure protective buffer zones for pesticides to prevent discriminatory effects on Native Hawaiians. With respect to all pesticides—both general use pesticides (GUPs) and restricted use pesticides (RUPs)—H.R.S. Chapter 149A authorizes HDOA to promulgate rules "[t]o establish limitations and conditions for the application of pesticides by aircraft, power rigs, mist blowers, and other equipment," and "[t]o establish, as necessary, specific standards and guidelines which specify those conditions which constitute unreasonable adverse effects on the environment," among other things. H.R.S. § 149A-33.

With respect to RUPs, HDOA may promulgate rules "establish[ing] fees, procedures, conditions, and standards to certify persons for the use of restricted use pesticides under section 4 of FIFRA." *Id.* § 149A-33. RUPs are classified as such if it they are "determined to be a health hazard," "can be reasonably anticipated to result in contamination of groundwater or significant reductions in nontarget organisms, or fatality to members of endangered species," have certain levels of toxicity, or are categorized as RUPs under federal law. H.A.R. § 4-66-32(b).

Although pesticide applications on Kaua'i and Moloka'i occur dangerously close to schools, residential areas, and surface waters, HDOA does not require protective buffer zones in

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[11] Pesticide Use by Large Agribusiness on Kaua'i, Findings and Recommendations of The Joint Fact Finding Study Group (May 25, 2016) at 87 (JFF Report).

[12] *Id.*

[13] *Id.* at 80-81.

[14] *See* Declaration of Howard Hurst ¶ 6, *Syngenta Seeds v. Cnty. of Kaua'i*, No. 1:14-cv-00014 (BMK) (D. Haw. Feb. 17, 2014) (attached as Ex. 9).

[15] JFF Report at 81.

its regulation of pesticides. In fact, HDOA has actively opposed proposed state legislation to require protective buffer zones. Some pesticide users in Hawai'i claim to use buffer zones for RUPs, but these zones are voluntary, unenforceable, and in any event inadequate to protect public health and safety. For example, the voluntary "Kaua'i Good Neighbor Program" establishes a mere 100-foot buffer zone between areas treated with RUPs and schools, medical facilities, and residential properties.[16] Yet, among the nation's top 25 largest agricultural production counties, buffer zones between RUP application and schools are at least 200 feet, and some are 5,280 feet (1 mile).[17] Fresno County, California, requires a buffer zone of 660 (1/8 mile) for all pesticides when school is in session.[18] In these counties, buffer zones for bees range from 100 feet to 4.5 miles (23,760 feet).[19] By failing to require, implement, and enforce *any* buffer zones whatsoever between pesticide application and Native Hawaiian communities, HDOA is violating Title VI.

[16] Kaua'i Agricultural Good Neighbor Program: Voluntary Standards and Guidelines for RUP Use Reporting and Buffer Zones (Nov. 12, 2013).

[17] JFF Report at 232-34.

[18] *Id.* at 232.

[19] *Id.* at 232-34.

Fig. 1. Proximity of Schools to RUPs on Kaua'i (Source: CFS Report)

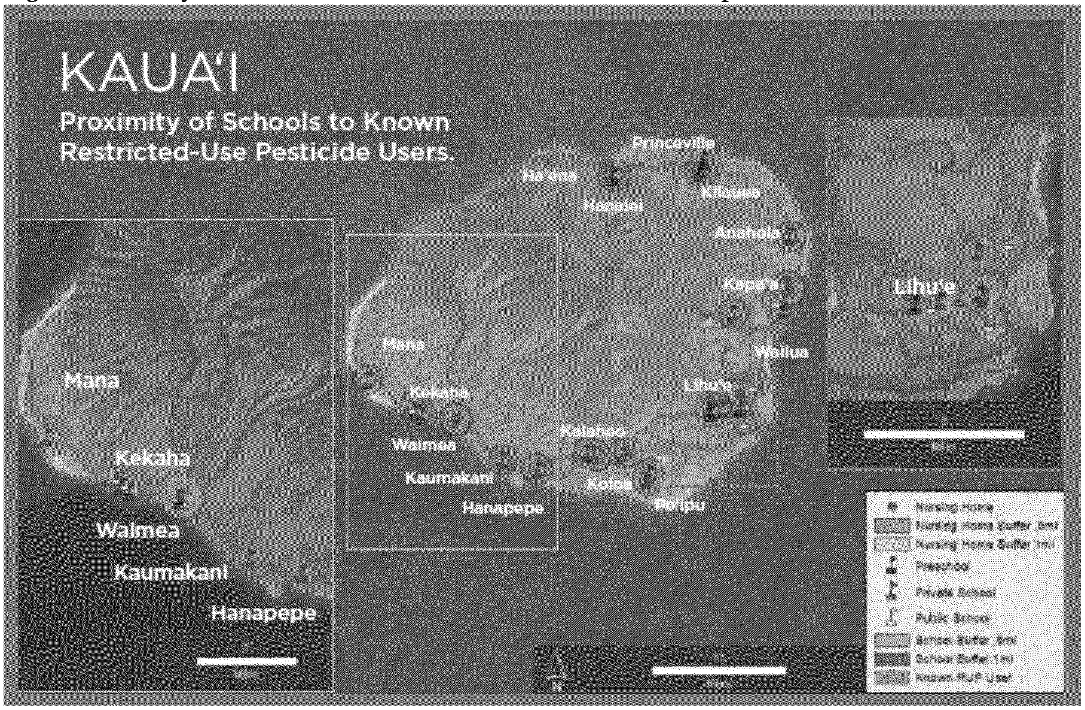
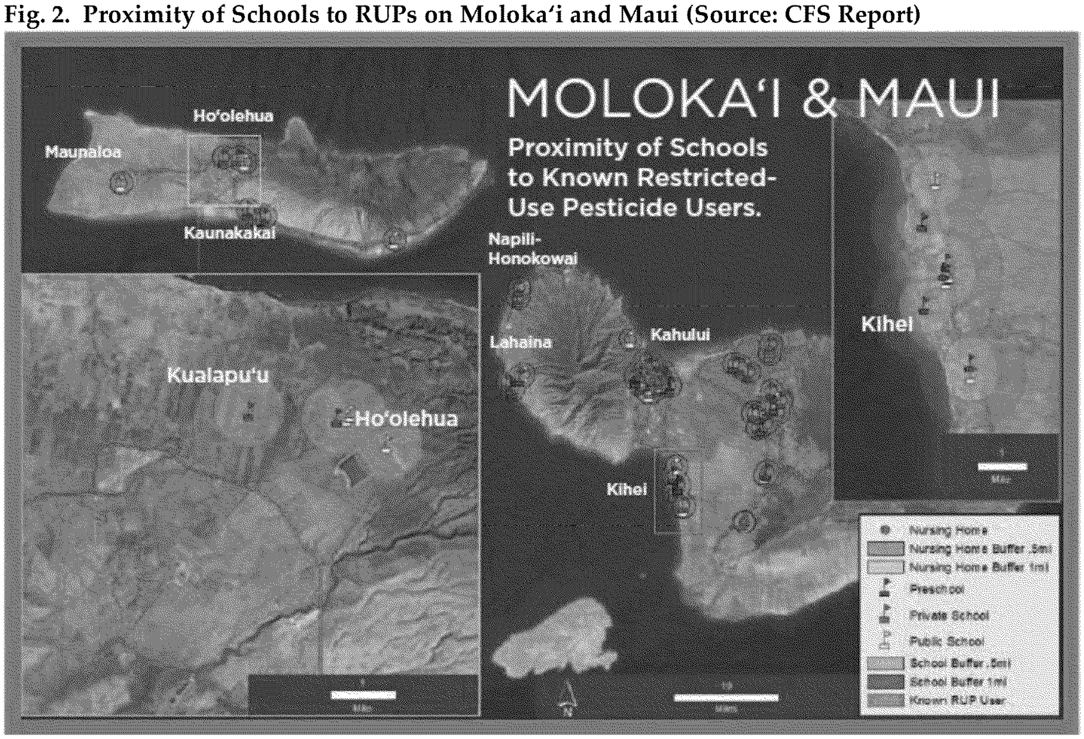


Fig. 2. Proximity of Schools to RUPs on Moloka'i and Maui (Source: CFS Report)



D. HDOA Is Failing To Enforce Federal and State Pesticides Laws.

HDOA is violating Title VI by failing to enforce the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), which disproportionately harms Native Hawaiians. FIFRA regulates pesticide distribution and use to prevent unreasonable adverse effects on the environment. 7 U.S.C. § 136a. Under 7 U.S.C. § 136w-1, the EPA Administrator may delegate primary enforcement responsibility for pesticide use violations. HDOA has primary authority to enforce FIFRA and the Hawaiʻi Pesticides Law, H.R.S. Chapter 149A. Accordingly, HDOA must implement adequate procedures to enforce these laws. 7 U.S.C. §§ 136w-1, -2.

HDOA is failing to enforce pesticide use violations under FIFRA and the Hawaiʻi Pesticides Law. HDOA has had a backlog of investigation files that has been increasing every year, with very few complaints resulting in enforcement actions, referred to the EPA, or addressed in any meaningful way.

EPA has repeatedly warned HDOA that its enforcement efforts are inadequate. EPA's 2012 performance review of HDOA recommended that HDOA hire an additional case development officer to assist with case file review.[20] EPA's 2013 review expressed significant concern regarding HDOA's backlog and decrease in enforcement activity, and recommended HDOA find ways to address them.[21] EPA's 2014 review noted that HDOA "continue[d] to have significant concerns with the backlog of inspection files to be processed, and the resulting lack of enforcement actions issued, as well as the lack of inspections forwarded to EPA for review/enforcement."[22] EPA's 2015 review revealed that there were approximately 700 inspection files in need of review, some dating back to 2008.[23] Some cases eventually referred to EPA that would have qualified for enforcement action were closed because the statute of limitations had expired.[24] EPA further noted the declining quality of the few inspections and reports HDOA had managed to produce and recommended improvement in that area, as well.[25] EPA also observed a significant increase in the number of pesticide-related complaints HDOA had received from individuals and groups throughout Hawaiʻi, focusing primarily on the

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[20] U.S. Environmental Protection Agency, Hawaii Department of Agriculture FY2012 End-of-Year Review, Pesticide Performance Partnership Grant at 7 (attached as Ex. 10).

[21] U.S. Environmental Protection Agency, Hawaii Department of Agriculture FY2013 Draft End-of-Year Review, Pesticide Performance Partnership Grant at 3 (attached as Ex. 11).

[22] U.S. Environmental Protection Agency, Hawaii Department of Agriculture FY2014 End-of-Year Review, Pesticide Performance Partnership Grant at 9 (attached as Ex. 12).

[23] U.S. Environmental Protection Agency, Hawaii Department of Agriculture FY2015 Final End-of-Year Review, Pesticide Performance Partnership Grant at 7 (attached as Ex. 13).

[24] *Id*.

[25] *Id*. at 4.

misuse of pesticides by large agrochemical companies.[26] By failing to adequately enforce federal and state pesticides laws, HDOA is violating Title VI.

E. ADC Is Leasing or Licensing State Lands Without Protecting Communities From Pesticides.

ADC is violating Title VI by leasing or licensing state lands in a manner that fails to protect nearby communities, including Native Hawaiians, from heavy pesticide use. The Hawai'i legislature created ADC in 1994 in the wake of the decline of the sugar and pineapple industries, for the purpose of "creat[ing] a vehicle and process to make optimal use of agricultural assets for the economic, environmental, and social benefit of the people of Hawaii." H.R.S. § 163D-1. To further that goal, ADC has the power to "sell, assign, exchange, transfer, convey, lease, or otherwise dispose of" real property, *id.* § 163D-4(7), and adopt rules to carry out its powers and duties, *id.* § 163D-4(4).

ADC has failed to adopt or implement *any* limits on its leasing and licensing program to protect health and the environment from heavy pesticide use. Instead, ADC leases or licenses the majority (64%)[27] of the thousands of acres it manages in West Kaua'i to pesticide-intensive seed companies, without any meaningful restrictions. By failing to adopt or implement measures to limit leasing or licensing to pesticide-intensive operations or prevent resulting harm to nearby communities, ADC is violating Title VI.

[26] *Id*. at 3.
[27] JFF Report at 165.

Fig. 3. ADC Kekaha Map License Agreements (Source: JFF Report)

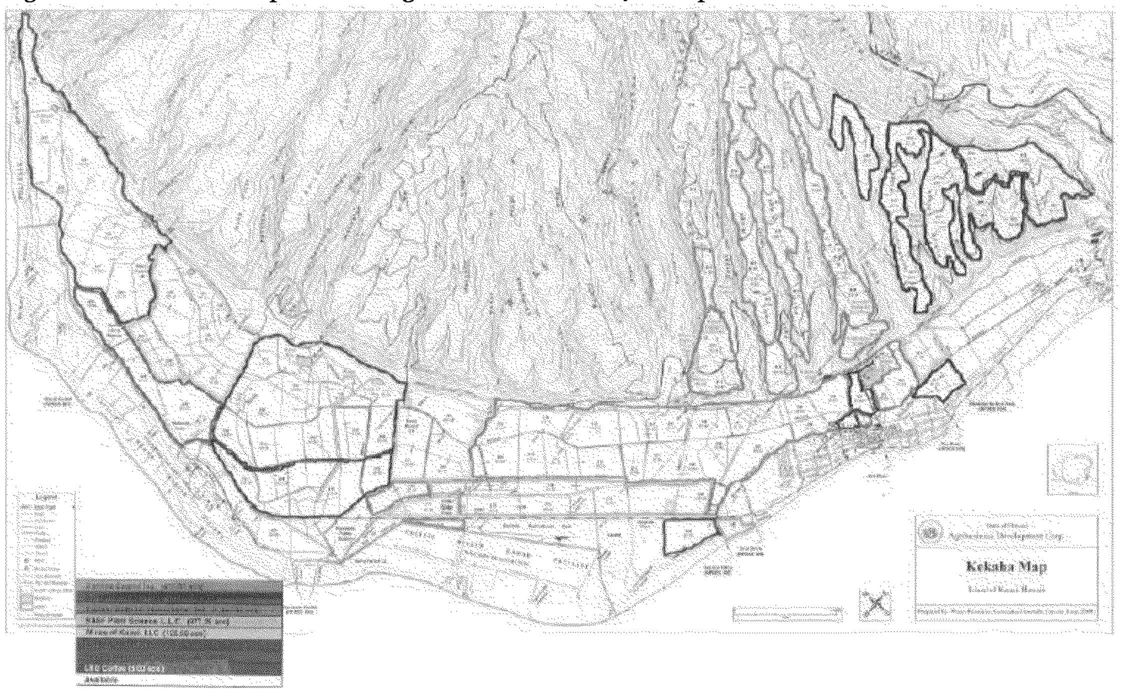
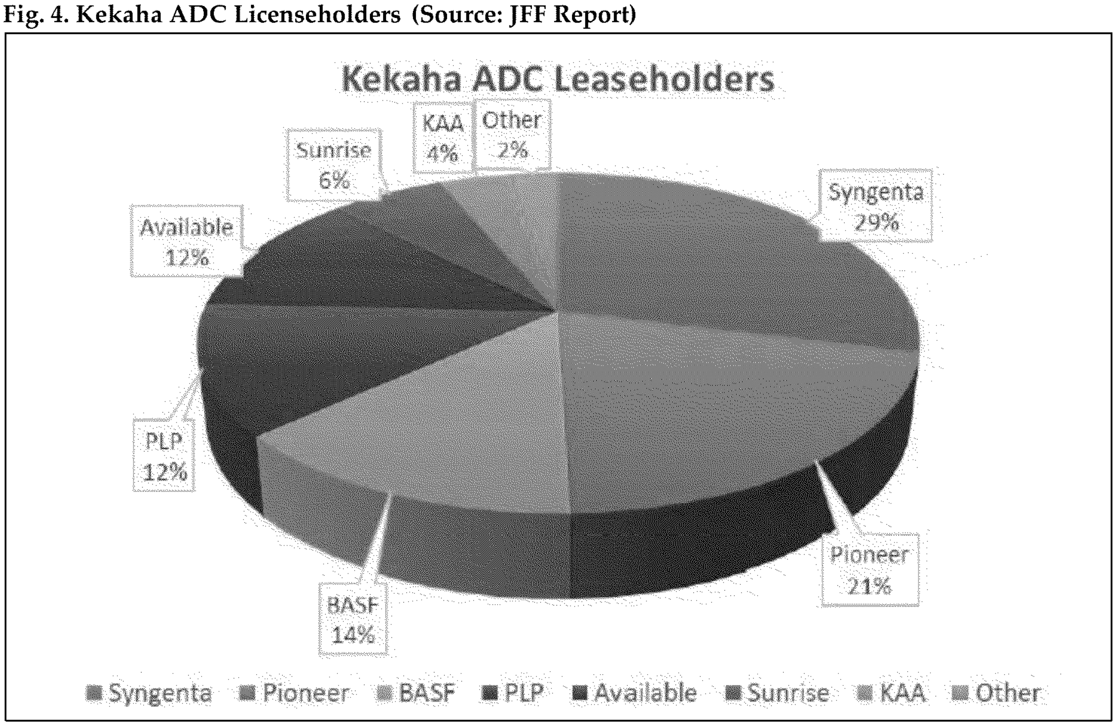


Fig. 4. Kekaha ADC Licenseholders (Source: JFF Report)



F. ADC is Refusing to Comply With the Clean Water Act.

ADC is violating Title VI by discharging pollutants without the requisite National Pollutant Discharge Elimination System (NPDES) permit, to the detriment of Native Hawaiians in West Kauaʻi. The federal Clean Water Act prohibits the discharge of pollutants into jurisdictional waters in the absence of an NPDES permit. 33 U.S.C. §§ 1311(a), 1362, 1342.

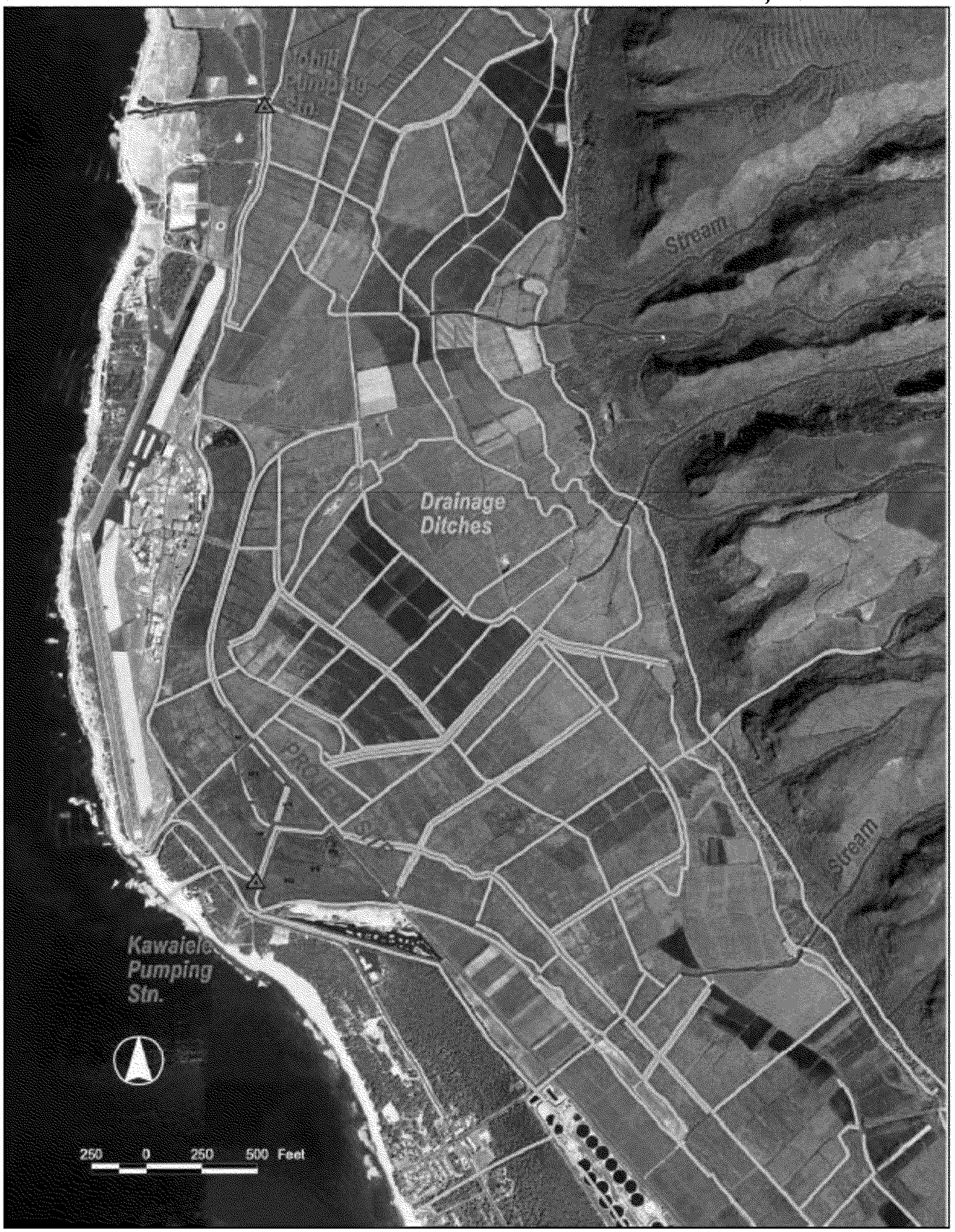
ADC operates a drainage ditch system on the Mānā Plain, located on the West Side of Kauaʻi. The drainage ditch system includes 40 miles of canals, 2 pumping stations, and 7 drainage ditch outfalls. In addition to genetically engineered seed crop fields, the Pacific Missile Range Facility, Sunrise Capital Shrimp Farm, Kekaha Landfill, former Kekaha Sugar Mill, Waimea Wastewater Treatment Plant, and Kauaʻi Raceway Park occupy Mānā Plain lands drained by the ditch system.

For decades, that State of Hawaiʻi Department of Health (HDOH) regulated ADC's discharges from the drainage ditch system under an NPDES permit, until August 3, 2015, when ADC withdrew its NPDES permit renewal application.[28] Now, millions of gallons of drainage waters containing toxic pollutants flow through the system and populated areas, and into the nearshore ocean waters, without any regulation or monitoring. HDOH's and HDOA's testing has shown the presence of harmful pesticides including atrazine, chlorpyrifos, glyphosate, and metolachlor in the drainage ditches, in addition to many other pollutants.

These unregulated and unmonitored discharges are of particular concern since Native Hawaiians gather limu and fish in these areas. The open ditches are not fenced off or marked with warning signs to prevent children from playing in them. The outfalls funnel polluted waters into areas popular for fishing surfing, swimming, and boating. ADC's unpermitted drainage ditch system in the heart of Kekaha and the surrounding recreational areas has a discriminatory effect on Native Hawaiians and therefore violates Title VI.

[28] Email from James Nakatani, State of Haw. Agribus. Dev. Corp. to Alec Wong, State of Haw. Dep't of Health, Aug. 3, 2015 (attached as Ex. 14).

Fig. 5. Mānā Plain Drainage Ditch System and Pump Stations
(Source: Final Environmental Assessment Mānā Plain Wetland Restoration Project)



VI. DISCRIMINATORY ADVERSE IMPACTS

Pesticide use generally, and specifically use of RUPs, adversely affects Native Hawaiian communities on Kaua'i and Moloka'i.

A. Pesticide Use on Kaua'i and Moloka'i

Kaua'i and Moloka'i are subjected to heavy pesticide use. On Kaua'i, active ingredient applications of RUPs and GUPs combined exceed 80,000 pounds annually,[29] and on most days, there are at least 30 pesticide spray operations.[30]

Adverse health effects from pesticide exposure are well-documented. Proximity to agricultural fields and maternal exposure to pesticides during pregnancy have been associated with central nervous system anomalies, oral cleft, and limb defects.[31] Pesticides have been strongly linked with asthma diagnosis in children under the age of five years of age,[32] and also linked with leukemia and an increased risk of brain tumors.[33] Men exposed to pesticides from fruits and vegetables have been found to have lower sperm counts than those who consume an organic diet.[34] Exposure to organophosphates such as chlorpyrifos during pregnancy is associated with decreases in IQ, increases in pervasive developmental disorders, attention deficit disorders, preterm birth, decreases in birth weight, and intrauterine retardation.[35]

On Kaua'i and Moloka'i, pesticide drift and windblown dust present problems for community members located near agricultural fields. A 2003 USGS survey observed that pesticides become attached to wind-blown dust.[36] Extremely fine dust can penetrate the lungs and cause bronchitis.[37] In West Kaua'i, physicians encounter "almost daily reports of respiratory symptoms in patients that have no history of these respiratory illnesses," nose bleeds in children, recurring dermatitis, "metallic taste" in patients' mouths, and high levels of infertility and gout.[38] *See also* Chun decl. ¶ 4-5. Residents of Moloka'i have experienced the same symptoms. *See* Ritte decl. ¶ 2-3.

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[29] CFS Report at 32.
[30] *Id.* at 30.
[31] JFF Report at 243.
[32] *Id.* at 243.
[33] *Id.* at 244.
[34] *Id.* at 246.
[35] *Id.* at 242-43.
[36] CFS Report at 39.
[37] *Id.*
[38] *Id.*

B. RUP Use on Kauaʻi and Molokaʻi

Large agrochemical and other companies apply RUPs heavily on Kauaʻi and Molokaʻi, to the great detriment of nearby communities and their members. On Kauaʻi from 2010 to 2012, RUP applications involved 22 RUPs containing 18 active ingredients and amounted to about 20,801 pounds of active ingredients annually.[39] The Joint Fact Finding Study Group estimated that from December 2013 to July 2015, Kauaʻi's five major agricultural pesticide users—BASF Plant Science, Dow AgroScience, DuPont Pioneer, Syngenta, and Kauaʻi Coffee Co., LLC[40]—applied 23 RUPs containing 15,072 pounds of 15 active ingredients.[41] RUP use data for these five companies is available through the "Kauaʻi Agricultural Good Neighbor Program."[42]

Molokaʻi is also subjected to high pesticide use. From 2013 to 2015, Monsanto applied around 10,050 pounds of 24 RUPs containing 17 active ingredients on Molokaʻi and Maui.[43] Although Monsanto reports only aggregate numbers for its RUP use on both islands, pesticide-intensive seed crop acreage on Molokaʻi (2,342 acres) is more than triple that on Maui (754 acres), which is much larger and has a much lower proportion of Native Hawaiians.[44] Dow Chemical, the only other agrochemical company with operations on Molokaʻi, does not report its pesticide use for the island.[45] Although pesticide users apply many types of RUPs on Kauaʻi and Molokaʻi, some of the most heavily used and toxic RUPs include chlorpyrifos, atrazine, metolachlor, bifenthrin, and paraquat dichloride, discussed below.

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[39] *Id.* at 32.

[40] According to Kauaʻi Coffee Co., LLC's voluntary reporting through the Good Neighbor Program, the only RUP the company applies is paraquat dichloride.

[41] JFF Report at 23.

[42] Kauaʻi Agricultural Good Neighbor Program, Aggregate usage of Restricted Use Pesticides as reported through the Kauaʻi Good Neighbor Program, https://data.hawaii.gov/Health/Kaua-i-Agricultural-Good-Neighbor-Program-RUP-Use-/9pud-c8q5 (last visited Aug. 16, 2016) (Kauaʻi GNP).

This data does not account for all RUP use or *any* GUP use on Kauaʻi.

[43] Monsanto Hawaii, 2013 Annual Report Maui County Memorandum of Understanding at 17-18 (2013 Monsanto Report); Monsanto Hawaii, 2014 Annual Report Maui County Memorandum of Understanding at 26 (2014 Monsanto Report); Monsanto Hawaiʻi, 2015 Annual Report Maui County Memorandum of Understanding at 25 (2015 Monsanto Report).

Monsanto's reported pesticide use was converted to pounds by multiplying the gallons used by the pounds of active ingredient per gallon, according to EPA's pesticide labels.

[44] State of Haw. Dep't of Agric., Statewide Agricultural Land Use Baseline 2015 at 47 (2015 Ag. Baseline).

[45] CFS Report at 19.

1. Chlorpyrifos

Chlorpyrifos is an organophosphate pesticide commonly used on corn fields that can over stimulate the nervous system, causing nausea, dizziness, confusion, respiratory paralysis, and death.[46] It is also a developmental neurotoxicant, exposure to which can cause structural abnormalities and persistent neurobehavioral deficits.[47] Studies have shown that juveniles are more susceptible to organophosphate toxicity than adults.[48] For children ages three to five, chlorpyrifos exposure may be associated with birth defects, autism, developmental delay, and attention deficit disorders.[49] Early life exposure to organophosphates including chlorpyrifos has been associated with higher levels of respiratory symptoms and exercise-induced coughing, consistent with possible asthma.[50] Children exposed to high levels of chlorpyrifos are more likely to suffer from attention deficit hyperactivity disorder and pervasive developmental disorder problems at three years of age.[51] A California study showed a 60% increase in autism in the children of mothers who lived slightly less than one mile from areas sprayed with organophosphates and chlorpyrifos.[52] EPA is currently considering revoking all chlorpyrifos tolerances because of its health risks.[53]

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[46] U.S. Environmental Protection Agency, Related Topics: Ingredients Used in Pesticide Products, Chlorpyrifos, https://www.epa.gov/ingredients-used-pesticide-products/chlorpyrifos (last visited Aug. 16, 2016).

[47] Philippe Grandjean & Philip J. Landrigan, Neurobehavioural effects of developmental toxicity, The Lancet, Feb. 14, 2014, http://www.thelancet.com/journals/laneur/article/PIIS1474-4422%2813%2970278-3/fulltext (last visited Aug. 16, 2016).

[48] Jie Zhang et al., Neonatal chlorpyrifos exposure induces loss of dopaminergic neurons in young adult rats, Toxicology 336, July 26, 2015, http://www.sciencedirect.com/science/article/pii/S0300483X15300196 (last visited Aug. 16, 2016).

[49] JFF Report at 60.

[50] Rachel Raanan et al., Early-life Exposure to Organophosphate Pesticides and Pediatric Respiratory Symptoms in the CHAMACOS Cohort, Environmental Health Perspectives 123:2, Feb. 2015, http://ehp.niehs.nih.gov/1408235/#tab1 (last visited Aug. 19, 2016).

[51] Virginia A. Rauh et al., Impact of Prenatal Chlorpyrifos Exposure on Neurodevelopment in the First 3 Years of Life Among Inner-City Children, Pediatrics 118:6, Dec. 2006.

[52] Janie F. Shelton et al., Neurodevelopmental Disorders and Prenatal Residential Proximity to Agricultural Pesticides: The CHARGE Study, Environmental Health Perspectives 122:10, Oct. 2014, http://ehp.niehs.nih.gov/1307044/ (last visited Aug. 16, 2016)

[53] U.S. Environmental Protection Agency, Related Topics: Ingredients Used in Pesticide Products, Revised Human Health Risk Assessment on Chlorpyrifos, https://www.epa.gov/ingredients-used-pesticide-products/revised-human-health-risk-assessment-chlorpyrifos#risk assessment (last visited Aug. 16, 2016).

From December 2013 to June 2016, agrochemical companies applied more than 3,700 pounds of chlorpyrifos on Kauaʻi,[54] and from 2013 to 2015, Monsanto applied more than 1,900 pounds of the same on Molokaʻi and Maui.[55] In West Kauaʻi, chlorpyrifos has been detected in the air near Waimea Canyon Middle School and near Kekaha and Waimea and in drainage ditches.[56] In addition, testing studies found chlorpyrifos at 90 ng/m^3 using a drift catcher 1,500 feet from the nearest agrochemical company field.[57] The Joint Fact Finding Study Group found that the rate of chlorpyrifos application on Kauaʻi is 2.93 times the rate on the continental United States.[58] Reported chlorpyrifos application rates on Kauaʻi are 2.5 lb. of active ingredient per acre per season for Cobalt Advanced and 3 lb. of active ingredient per acre per season for Lorsban Advanced.[59]

2. Atrazine

Atrazine is a "highly potent" endocrine disruptor that is mobile and persists in the environment after its use.[60] It causes adverse reproductive effects even at concentrations as low as 0.1 ppb.[61] Atrazine can cause reproductive difficulties and cardiovascular problems in humans. 40 C.F.R. Pt. 141, Subpt. O, App. A; H.A.R. § 11-20 App. A. According to the U.S. Department of Health and Human Services, Agency for Toxic Substances and Disease Registry (ATSDR), atrazine exposure in animals during pregnancy causes reduced fetus survival.[62] Maternal exposure to surface water atrazine is associated with fetal gastroschisis.[63] Atrazine has been shown to decrease egg production and cause gonad abnormalities in fish.[64] ATSDR warns that "[i]n areas of high atrazine use, individuals should avoid swimming in or drinking from contaminated water sources and may desire to have personal well water tested for the presence of atrazine," and that "[c]hildren should avoid playing in soils near uncontrolled hazardous

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[54] Kauaʻi GNP.

[55] 2013 Monsanto Report at 17; 2014 Report at 25; 2015 Monsanto Report at 26.

[56] JFF Report at 193-94.

[57] *Id.* at 40.

[58] *Id.* at 29.

[59] *Id.* at 175, 177.

[60] *Id.* at 192.

[61] *Id.*

[62] Agency for Toxic Substances & Disease Registry, Public Health Statement for Atrazine, CAS#: 1912-24-9, Sept. 2003, *available at*, http://www.atsdr.cdc.gov/phs/phs.asp?id=336&tid=59 (Atrazine Public Health Statement).

[63] Sarah A. Waller et al., Agricultural-related chemical exposures, season of conception, and risk of gastroschisis in Washington State, American Journal of Obstetrics and Gynecology 203:183, Aug. 2010.

[64] Donald E. Tillitt et al. Atrazine reduces reproduction in fathead minnow (Pimephales promelas), Aquatic Toxicology 99:2, Aug. 2010.

waste sites where atrazine may have been discarded."[65] In 2004, the European Union banned products containing atrazine, concluding that the levels of atrazine would "have an unacceptable effect on groundwater."[66]

From December 2013 to June 2016, agrochemical companies applied more than 2,500 pounds of atrazine on Kauaʻi,[67] and from 2013 to 2015, Monsanto applied more than 1,440 pounds of the same on Molokaʻi and Maui.[68] For 2014 to 2015, 99.8% of the state's atrazine sales occurred in Kauaʻi and Maui counties.[69] In West Kauaʻi, atrazine was detected in the drinking water at Waimea Canyon Middle School, and in irrigation water and surface water in amounts that exceed aquatic life benchmarks.[70] A recent EPA assessment of atrazine acknowledged that "atrazine is expected to leach to ground water and move to surface water through runoff and spray drift."[71]

3. Metolachlor

Studies have associated metolachlor with reduced cell growth,[72] and it has been classified by the EPA as a class C carcinogen.[73] From December 2013 to June 2016, agrochemical companies applied more than 7,400 pounds of metolachlor on Kauaʻi,[74] and from 2013 to 2015, Monsanto more than 2,100 pounds of the same on Molokaʻi and Maui.[75] For 2014 to 2015, 83.1%

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[65] Atrazine Public Health Statement at 2.

[66] 2004/248/EC: Commission Decision of 10 March 2004 concerning the non-inclusion of atrazine in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing this active substance, *available at* http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32004D0248.

[67] Kauaʻi GNP.

[68] 2013 Monsanto Report at 17; 2014 Monsanto Report at 25; 2015 Monsanto Report at 26.

[69] State of Hawaiʻi Department of Agriculture, Summary of Restricted Use Pesticides Sold in 2014 (2014 RUP Sales); State of Hawaiʻi Department of Agriculture, Summary of Restricted Use Pesticides Sold in 2015 (2015 RUP Sales).

[70] JFF Report at 193.

[71] U.S. Environmental Protection Agency, Office of Chemical Safety and Pollution Prevention, Refined Ecological Risk Assessment for Atrazine, Apr. 12, 2016.

[72] S. Echeverrigaray et al., Isolation and characterization of Metolachlor-resistant mutants of Saccharomyces cerevisiae, World Journal of Microbiology and Biotechnology 15:6, Dec. 1999; Dana M. Lowry et al., Mechanism of metolachlor action due to alterations in cell cycle progression, Cell Biology and Toxicology 29:4, Aug. 2013.

[73] U.S. National Library of Medicine, Toxnet Toxicology Data Network, Metolachlor, https://toxnet.nlm.nih.gov/cgi-bin/sis/search/a?dbs+hsdb:@term+@DOCNO+6706 (last visited Aug. 17, 2016).

[74] Kauaʻi GNP.

[75] Monsanto 2013 Report at 17; Monsanto 2014 Report at 25; Monsanto 2015 Report at 26.

of the state's metolachlor sales occurred in Kauaʻi and Maui counties.[76] In West Kauaʻi, metolachlor was detected in the air near Waimea Canyon Middle School,[77] and has been found in surface water near Kīkīaʻola Boat Harbor at rates that exceed EPA's aquatic life benchmarks.[78]

4. Bifenthrin

EPA has classified bifenthrin as a class C carcinogen.[79] From July 2014 to March 2016, BASF Plant Science applied 0.887 pounds of bifenthrin on Kauaʻi.[80] The Joint Fact Finding Study Group found that the rate per acre of bifenthrin application on Kauaʻi is 5.36 times the rate in the continental United States.[81] The same study found that, based on EPA analysis, bifenthrin has a high potential for volatilization (vaporization), which increases the chance of pesticide drift in the air.[82] Bifenthrin has been detected in the air near Waimea Canyon Middle School.[83]

5. Paraquat Dichloride

From January 2014 to June 2016, major pesticide users applied more than 2,500 pounds of paraquat dichloride on Kauaʻi,[84] and from 2013 to 2015, Monsanto applied more than 310 pounds of the same on Molokaʻi and Maui.[85] The European Union has banned paraquat dichloride since 2007.[86] According to EPA, paraquat dichloride is highly toxic to humans, and is

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[76] 2014 RUP Sales; 2015 RUP Sales.
[77] JFF Report at 193-94.
[78] *Id.* at 194.
[79] U.S. National Library of Medicine, Toxnet Toxicology Data Network, Bifenthrin, https://toxnet.nlm.nih.gov/cgi-bin/sis/search/a?dbs+hsdb:@term+@DOCNO+6568 (last visited Aug. 17, 2016).
[80] Kauai GNP.
[81] JFF Report at 29.
[82] *Id.* at 39.
[83] *Id.* at 193.
[84] Kauaʻi GNP.
[85] 2014 Monsanto Report at 17; 2014 Monsanto Report at 25; 2015 Monsanto Report at 26.
[86] European Union, The Court of First Instance Annuls the Directive Authorising Paraquat as an Active Plant Protection Substance, July 11, 2007.

corrosive to the skin and eyes.[87] A 2011 National Institute of Health study demonstrated an association between paraquat dichloride use and Parkinson's disease in farm workers.[88]

VII. DISPROPORTIONALITY

HDOA and ADC's discriminatory actions and inactions with respect to pesticides and the resulting adverse impacts disproportionally harm Native Hawaiians in West Kauaʻi and on Molokaʻi. The majority of the state's pesticide-intensive production occurs in these particular regions, which are also home to large populations of Native Hawaiians. Kauaʻi bears the burden of more than half of the state's seed production (56% or 13,299 of 23,728 acres), and the great majority (78.1%) of this production is found on the West Side in the Kekaha-Waimea (5,455 acres) and Kaumakani-Hanapepe (4,932 acres) regions.[89] The Native Hawaiian populations in the Kekaha-Waimea (37.2%) and Kaumakani-Hanapepe (28.8%) regions are proportionally the second and third largest on the island and significantly exceed the island-wide (23.9%) and statewide (21.3%) percentages.[90] In the Kekaha-Waimea region, the percentage of pure Native Hawaiians (12.4%) exceeds the island-wide percentage (7.4%) and more than doubles the statewide percentage (5.9%).[91] By contrast, the white alone populations in the Kaumakani-Hanapepe (14.8%) and Kekaha-Waimea (19.8%) regions are proportionally the first and third smallest on the island and are significantly less than the island-wide (33.1%) and statewide (24.7%) percentages.[92] The seed fields in West Kauaʻi surround the Hawaiian Home Lands of Kekaha and border the Hawaiian Home Lands of Hanapepe as well as the largest tract of Hawaiian Home Lands on the island, Waimea.[93]

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[87] U.S. Environmental Protection Agency, Paraquat Dichloride, https://www.epa.gov/ingredients-used-pesticide-products/paraquat-dichloride (last visited Aug. 16, 2016).

[88] Caroline Tanner et al., Rotenon, Paraquat, and Parkinson's Disease, Environmental Health Perspectives 119:6, June 2011, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3114824/ (last visited Aug. 16, 2016).

[89] 2015 Ag. Baseline at 47, 49.

[90] State of Haw. Dep't of Business, Econ. Dev. & Tourism, Native Hawaiian Population by County, Island and Census Tract in the State of Hawaiʻi: 2010 (Feb. 2012) at 9, 15 (2010 Native Hawaiian Census).

[91] *Id.*

[92] State of Haw. Dep't of Business, Econ. Dev. & Tourism, Population by Major Race Categories Alone or in Combination by County and Census Tract, State of Hawaiʻi: 2010 (2010 Hawaiʻi Race Census).

[93] 2010-2014 American Community Survey 2014, Hawaiian Home Land Areas (2014 DHHL ACS).

Seed crops occupy 2,342 acres on Molokaʻi, right in the center of the island near several populated areas, public schools, and preschools.[94] The seed fields border the island's most populated tract of Hawaiian Home Lands, Hoʻolehua-Pālāʻau (pop. 1,327), and the Hawaiian Home Lands tract Kalamaʻula.[95] The majority of Molokaʻi residents are Native Hawaiian.[96] Molokaʻi has the second highest percentage of Native Hawaiians among all of the islands in the state.[97] Molokaʻi's proportion of Native Hawaiians (61.6%) is nearly triple the statewide percentage (21.3%), and the proportion of pure Native Hawaiians (24.7%) is more than quadruple the statewide percentage (5.9%).[98] West Molokaʻi ranks fourth and East Molokaʻi ranks seventh out of all census tracts in the state for percentages of Native Hawaiians (67.8% and 58.1%), and West Molokaʻi ranks ninth for the percentage of pure Native Hawaiians (26.6%).[99] By contrast, the white alone population on Molokaʻi (16.2%) is significantly less than the statewide percentage (24.7%).[100]

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[94] 2015 Ag. Baseline at 47, 67.
[95] 2014 DHHL ACS.
[96] 2010 Native Hawaiian Census at 16.
[97] *Id.* at 6.
[98] *Id.*
[99] *Id.* at 7-8.
[100] 2010 Hawaiʻi Race Census.

Fig. 6. Hawaiian Populations, Hawaiian Home Lands, Seed Production, and Schools on Kaua'i

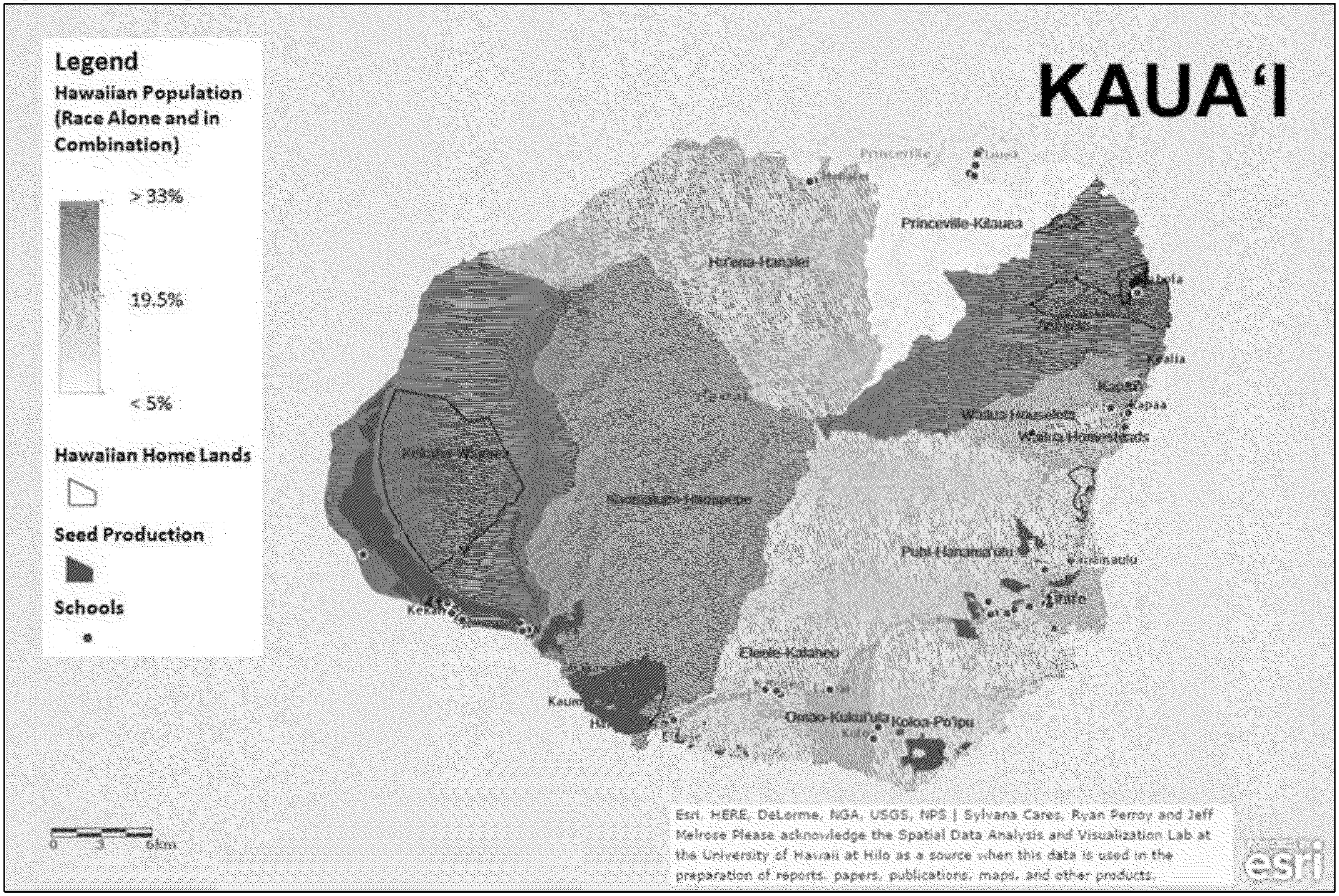
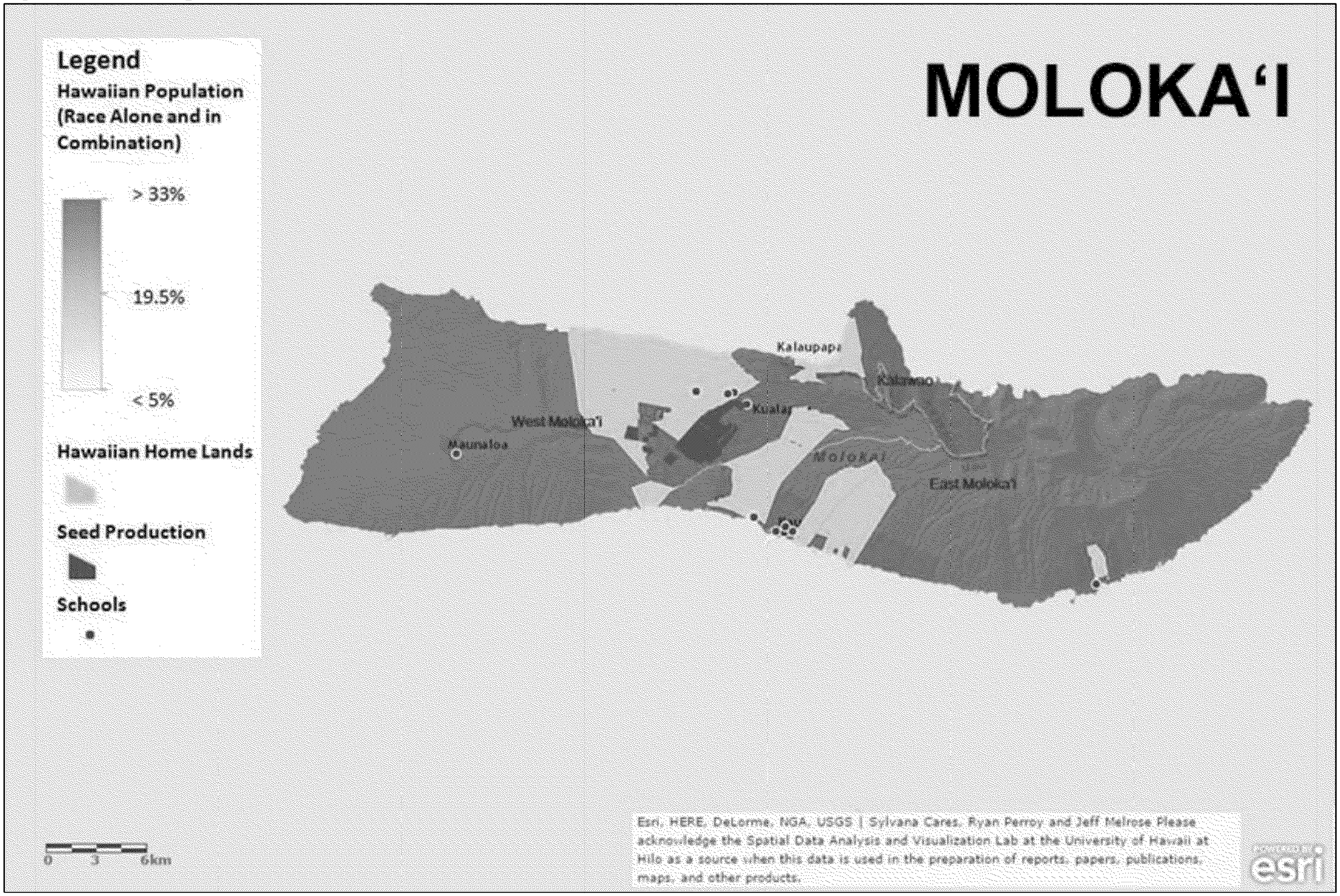


Fig. 7. Hawaiian Populations, Hawaiian Home Lands, Seed Production, and Schools on Moloka'i



Tbl. 2. Native Hawaiian and White Populations for State, Kauaʻi, and Molokaʻi, Census Data 2010

State, Island, 2010 census tract	Total population	Native Hawaiian alone	Native Hawaiian alone or in combination	% of Native Hawaiian alone	% of Native Hawaiian alone or in combination	White alone	White in combination	% of White alone	% of White in combination
State	**1,360,301**	**80,337**	**289,970**	**5.9**	**21.3**	**336,599**	**564,323**	**24.7**	**41.5**
Kauaʻi	**66,921**	**4,951**	**15,978**	**7.4**	**23.9**	**22,155**	**34,152**	**33.1**	**51.03**
Princeville-Kīlauea	6,484	210	629	3.2	9.7	4,366	5,063	67.3	78.1
Hāʻena-Hanalei	1,344	150	288	11.2	21.4	847	1,034	63.02	76.9
Wailua Houselots	5,047	324	1,154	6.4	22.9	2,387	3,348	47.3	66.3
Wailua Homesteads	3,845	252	816	6.6	21.2	1,496	2,220	38.9	57.7
Kapaʻa	8,385	585	2,176	7.0	26.0	2,386	4,145	28.5	49.4
Puhi-Hanamāʻulu	8,740	466	1,700	5.3	19.5	1,513	2,842	17.3	32.5
Līhuʻe	5,943	331	1,311	5.6	22.1	1,331	2,389	22.4	40.2
Kōloa-Poʻipū	2,544	151	466	5.9	18.3	937	1,321	36.8	51.9
ʻŌmaʻo-Kukuiʻula	3,139	205	723	6.5	23.0	1,195	1,813	38.1	57.8
ʻEleʻele-Kalāheo	8,403	317	1,611	3.8	19.2	2,927	4,584	34.8	54.6
Kaumakani-Hanapēpē	3,771	357	1,085	9.5	28.8	557	1,215	14.8	32.2
Kekaha-Waimea	5,561	690	2,069	12.4	37.2	1,101	2,246	19.8	40.4
Anahola	3,715	913	1,950	24.6	52.5	1,112	1,932	29.9	52.0
Molokaʻi	**7,345**	**1,811**	**4,527**	**24.7**	**61.6**	**1,192**	**2,924**	**16.2**	**39.8**
East Molokaʻi	4,503	1,042	2,616	23.1	58.1	784	1,861	17.4	41.3
West Molokaʻi	2,752	732	1,865	26.6	67.8	384	1,030	14	37.4
Kalawao	90	37	46	41.1	51.1	24	33	26.7	36.7

VIII. LESS DISCRIMINATORY ALTERNATIVES

Rather than implementing its programs and activities in a way that disproportionately adversely affects Native Hawaiians, HDOA and ADC have broad powers to instead take the following actions:

- HDOA and ADC could adopt and implement Title VI compliance programs to ensure that the agencies' policies, programs, and activities do not involve discriminatory treatment or have discriminatory effects on the basis of race, color, or national origin;
- HDOA could revoke or suspend pesticide licenses that have unreasonable adverse effects on health and the environment;
- HDOA could implement and enforce mandatory, adequately protective buffer zones between pesticide application and populated or heavily used areas like schools, medical facilities, and commercial areas;
- HDOA could adopt and implement EPA's recommendations to improve enforcement of federal and state pesticides laws;
- ADC could develop and implement criteria for evaluating applications for land licenses or leases to protect nearby communities from heavy pesticide use; and
- ADC could apply for, obtain, and comply with the terms of a valid NPDES permit.

Without implementing these measures, HDOA and ADC's activities and program will continue to disproportionately harm Native Hawaiians in West Kaua'i and on Moloka'i.

IX. RELIEF

Despite HDOA and ADC's obligations and powers under Title VI and state law, the agencies are doing remarkably little to correct this grave injustice. Accordingly, community groups request that EPA and USDA:

- Conduct a thorough Title VI compliance review of HDOA, particularly with respect to its implementation and enforcement of FIFRA and the Hawai'i Pesticides Law;
- Conduct a thorough Title VI compliance review of ADC with respect to its land management program and operation of the Mānā Plain drainage ditch system;
- Require HDOA and ADC to develop detailed inter- and intra-agency Title VI implementation plans that, at minimum, address less discriminatory alternatives and incorporate input from affected populations; and
- Oversee and ensure implementation of such plans on an annual basis.

These actions are necessary to bring HDOA and ADC into full compliance with Title VI.

We welcome the opportunity to meet with you to discuss the concerns and recommendations in this letter.

Sincerely,

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Pōʻai Wai Ola/West Kauaʻi Watershed Alliance

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EXHIBITS

Ex. 1 Declaration of Mercy Ritte

Ex. 2 Declaration of Malia Chun

Ex. 3 Request to Access a Government Record from Paul Achitoff, Earthjustice, to State of Haw. Dep't of Agric., Mar. 23, 2016

Ex. 4 Request to Access a Government Record from Paul Achitoff, Earthjustice, to State of Haw. Agribus. Dev. Corp., Mar. 23, 2016

Ex. 5 Letter from James Nakatani, State of Haw. Agribus. Dev. Corp. to Paul Achitoff, Earthjustice, Mar. 30, 2016

Ex. 6 Email from Bryan Yee, State of Haw. Dep't of Agric, to Paul Achitoff, Earthjustice, Apr. 27, 2016

Ex. 7 State of Haw. Dep't of Human Res. Dev., Policies and Procedures, Discrimination/Harassment-Free Workplace Policy, Policy No. 601.001, eff. Oct. 15, 2013

Ex. 8 State of Haw. Dep't of Agric., Department of Agriculture Limited English Proficiency Plan, July 1, 2013

Ex. 9 Declaration of Howard Hurst, *Syngenta Seeds v. Cnty. of Kaua'i*, No. 1:14-cv-00014 (BMK) (D. Haw. Feb. 17, 2014)

Ex. 10 U.S. Environmental Protection Agency, Hawaii Department of Agriculture FY2012 End-of-Year Review, Pesticide Performance Partnership Grant

Ex. 11 U.S. Environmental Protection Agency, Hawaii Department of Agriculture FY2013 Draft End-of-Year Review, Pesticide Performance Partnership Grant

Ex. 12 U.S. Environmental Protection Agency, Hawaii Department of Agriculture FY2014 End-of-Year Review, Pesticide Performance Partnership Grant

Ex. 13 U.S. Environmental Protection Agency, Hawaii Department of Agriculture FY2015 Final End-of-Year Review, Pesticide Performance Partnership Grant

Ex. 14 Email from James Nakatani, State of Haw. Agribus. Dev. Corp. to Alec Wong, State of Haw. Dep't of Health, Aug. 3, 2015

DECLARATION OF MERCY RITTE

I, Mercy Kaulanakapuananihemakanamaikeakua Ritte, declare that if called as a witness in this action I would testify of my own personal knowledge as follows:

1. I live in Hoʻolehua, Molokaʻi, with my husband and three children. I have lived on Molokaʻi almost all my life.

2. I first became interested in learning more about Monsanto and its operations on Molokaʻi about five years ago. Beginning in around October 2011, I noticed that Molokaʻi was experiencing very little rainfall. Yet, Monsanto continued to expand and plow the land, leaving much of it exposed to the elements. It was very common to see "dust devils" traveling across the landscape throughout the day. Less common, and baffling to me, was witnessing the largest dust storms ever on Molokaʻi! In early 2012, I remember the kona winds were picking the soil up from the exposed plots, and forming thick clouds of red dust, sending them miles and miles across the land. The dust from these clouds would not only end up on homes and yards, but go through open windows.

3. Shortly after these dust storms, my son, who was about seven months old at the time, awoke very early in the morning unable to breathe properly and was coughing uncontrollably. At first, I didn't know what to make of this

EXHIBIT 1

sickness. My husband and I began to retrace the events leading up to his mysterious cough. During the time of the dust storms we also noticed bright lights coming from the fields very early in the morning (1-2am). Concerned, my husband discovered that the field workers were plowing the fields at night. This pattern of plowing at night, the huge dust storms, and my son's sickness motivated me to research more about the company and its operations.

4. In September 2012, a small group of concerned Moloka‘i moms who had noticed similar problems from Monsanto's growing operations on Moloka‘i first gathered together to try to address them. We began to research what Monsanto was doing and discussed what we found with each other, and learned from others who had been following this issue. This group of moms stepped forward and took immediate action to join the rest of the world and participate in Occupy Monsanto, a week-long demonstration on Moloka‘i.

5. In January 2013, I met and connected with mothers throughout Hawai‘i who had learned what a small group of Moloka‘i moms were doing and who shared the same mission and love for their islands. Motivated by their determination and enthusiasm to make a difference I founded The Moms On a Mission Hui (The MOM Hui), which then emerged also on Kaua‘i, O‘ahu and Maui. The official The MOM Hui was founded in May 2013.

6. The MOM Hui is a grassroots group of forward-thinking mothers who advocate for protecting the health, safety, and well-being of all children, present and future. The MOM Hui is under the fiscal sponsorship of Hawai'i SEED, a 501(c)(3) non-profit organization and coalition of grassroots groups, farmers, and communities from five islands, who are working to educate the public about the risks posed by production of genetically engineered crops and to promote diverse, local, healthy, and ecologically sound food and farming. The MOM Hui's motto is "What We Love, We Will Protect!"

7. The MOM Hui supports:

- Food sovereignty and small-scale, local farmers who uphold natural farming practices and principles that improve soil and plant life, preserve Hawai'i's limited natural resources and enhances the quality of life and health for farmers and consumers;
- Sustainable and viable economic opportunities that provide safe, healthy long-term work for families;
- The right to make informed, confident choices about consumer products;
- The right to live and work in an environment that is non-threatening to the well-being of present and future generations;

- The right of people to define their own food systems and policies, rather than have them forced on them by corporations and marketing establishments.

8. To support its mission, The MOM Hui has engaged in:

- Community Outreach: It has hosted community events featuring documentary films and guest speakers, and informational tables at the Saturday market, and community events (i.e., Hoʻomau).
- Scholarship Program: It established a community-based scholarship program called Hoʻola Hou for Molokaʻi students enrolled in college and seeking a degree in health, environmental studies or organic/sustainable farming. Funds are raised through our annual grassroots benefit concert event and donations from the Tides Foundation.
- Community Marches/Rallies: It has organized and supported such events on Molokaʻi, Maui and Oʻahu to help educate and empower the community.
- Home gardening: Its vision includes collectively growing enough food to feed our community through a CSA (community-supported agriculture) operation, selling vegetable boxes.

- Workshops: It hosted a kiawe flour workshop, with guest experts to inform and inspire the community to learn about new sustainable agricultural products.
- Health Survey Project: It surveyed door-to-door, nearly 300 homes on Moloka'i to document current health conditions. This effort is ongoing and is extending to other parts of the island.
- Supporting the ballot initiative calling for a moratorium on genetically engineered crop production in Maui County until after an impact study is prepared.

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

Executed on Moloka'i on September 02, 2016.

Mercy Ritte

DECLARATION OF MAILA CHUN

1. My name is Malia Chun and I reside on the west side of Kaua'i in the town of Kekaha. I declare that if called as a witness in this action I would testify of my own personal knowledge as follows.

2. I received my B.A.in Hawaiian Studies and Education at the University of Hawai'i at Mänoa in 2000. I have been a Program Coordinator for a cultural enrichment program for Native Hawaiian children at the University of Hawai'i for 16 years.

3. Nine years ago I had the opportunity to build my own home in Kekaha. This is an opportunity that many young families, let alone single mothers such as myself, cannot afford to experience in Hawai'i. I packed my daughters Lei'ohu (13) and La'akea (10) up and we re-located to the opposite end of the island, Kekaha. Kekaha is a rural, close knit community, consisting of many 1st and 2nd generation plantation workers, fishermen, hunters and Ni'ihauians (natives of the island of Ni'ihau). At first, I saw this

EXHIBIT 2

transition as a blessing, an opportunity to raise my children in a safe, community-minded environment, just a block from beautiful white sand beaches and twenty minutes away from Koke'e State Park. Little did I know at the time that in a matter of three years I would be surrounded by test sites for genetically engineered crops, sprayed constantly with toxic chemicals year-round, even at night as we sleep.

4. The only thing that stands between my brand new home and these toxic chemicals is a polluted irrigation ditch. The sad fact is that I live in Hawaiian homesteads, among one of the largest pure Native Hawaiian, native speaking populations in the state of Hawai'i, people who are considered an endangered human race, and we are surrounded by and exposed to restricted use pesticides on a daily basis. What I have learned in the last seven years of being a resident of Kekaha is that the number of people who suffer from physical ailments on the west side of Kaua'i is astounding.

5. About five years ago, I started to notice I was suffering from a shortness of breath, and when I would catch a simple cold it would take me at least three weeks to recover. It was then that my doctor (Dr. Zimmerman) suggested that I may be experiencing an onset of adult asthma. This was around the same time that my daughter started to complain that she was experiencing headaches and occasional bloody noses when she woke up in the morning. When I took my daughter in to the doctor (Dr. Carolan), he couldn't explain what her symptoms may be from. Since then, I have also sought the professional advice of another doctor (Dr. Hackk), and he diagnosed me with adult asthma. Having no prior history of asthma or smoking, being physically active and having a very healthy diet, Dr. Hackk's only explanation was that my adult asthma was "environmental." There was very little I could do to remedy the problem because it was something I was constantly exposed to in my environment. I was advised

to continue to take Albuterol, an inhaler, and when things get really bad, to come in for steroid shots.

6. As a result of these physical ailments that my daughters and I started to experience five years ago and are still suffering from, I have taken it upon myself to educate my family and my community on the dangers of restricted use pesticides, how other countries have been affected through exposure, and how our food system has been compromised by genetically modified foods and by-products. I have been an active voice at protests, rallies, marches and hearings in trying to get bills passed that will protect our community and allow us the basic human rights of knowledge and protection. I have also rallied a group of west side families that have similar concerns. Together we plan educational events for our community and have made it a personal mission to install a food garden in one family's yard per month.

7. I am a member of The Mother on a Mission (MOM) Hui, a group of mothers who, like me, are concerned

about the health effects they and their ‘ohana have suffered from the dust and pesticides that drift into their homes and schools from nearby agricultural fields.

8. One of the issues I have been actively engaged in is supporting Bill 2491 passed by Kaua’i County, which would help protect me and my ‘ohana by requiring that the companies that spray pesticides near our home disclose what chemicals they are spraying and when they intend to spray it, and by preventing spraying close to my house and neighborhood through buffer zones. Bill 2491is a step in the right direction towards providing our community and my ‘ohana with some much needed and deserved answers, and working towards a cleaner, healthier future for our keiki and for Kaua‘i. Although a court declared Bill 2491 preempted by Hawai‘i law, I am hopeful that ruling will be overturned on appeal. One way or another I hope my ‘ohana and I and all of the other people who live near these fields will be given these basic protections.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Dated: September __, 2016, at Kekaha, Kaua'i, Hawai'i.

DS

MALIA CHUN

REQUEST TO ACCESS A GOVERNMENT RECORD

This is a model form that may be used by a Requester to provide sufficient information for an agency to process a record request. Although the Requester is not required to use this form or to provide any personal information, the agency needs enough information to contact the Requester with questions about this request or to provide its response. This request may not be processed if the agency has insufficient information or is unable to contact the Requester.

DATE: March 23, 2016

TO: Hawai'i Department of Agriculture
Agency that Maintains the Government Record

Hawaii Board of Agriculture
Office of the Chairperson
1428 S. King Street
Honolulu, HI 96814
Agency's Contact Information

FROM: Paul Achitoff
Requester's Name or Alias

Earthjustice
850 Richards Street, Suite 400
Honolulu, HI 96813
(808) 599-2436
Requester's Contact Information

AS THE REQUESTER, I WOULD LIKE THE FOLLOWING GOVERNMENT RECORD:

Describe the government record as specifically as possible so that it can be located. Try to provide a record name, subject matter, date, location, purpose, or names of persons to whom the record refers, or other information that could help the agency identify the record. A complete and accurate description of the requested government record will prevent delays in locating the record. Attach additional pages if needed.

Please provide a copy of any written material describing or documenting any Title VI compliance program(s) the Hawai'i Department of Agriculture has or is implementing to ensure that its actions do not involve discriminatory treatment and do not have discriminatory effects even when facially neutral, as described in Title VI of the Civil Rights Act of 1964, Title VI, 42 U.S.C. § 2000d et seq.

I WOULD LIKE: (Please check one or more of the options below, as applicable)

☐ **To inspect the government record**

X **A copy of the government record:** (Please check only one of the options below.) See the next page for information about fees and costs that you may be required to pay for agency services to process your record request. Note: Copying and transmission charges may also apply to certain options.

☐ Pick up at agency (**date and time**):
☐ Mail (address): ______
X E-mail (address): achitoff@earthjustice.org
☐ Fax (toll free and only if available; provide fax number): ______
☐ Other, if available (please specify): ______

EXHIBIT 3

X If the agency maintains the records in a form other than paper, please advise in which **format you would prefer to have the record**.

X Electronic ☐ Audio ☐ Other (please specify):____________________

X Check this box **if you are attaching a request for waiver of fees in the public interest** (See waiver information on next page).

FEES FOR PROCESSING PUBLIC RECORD REQUESTS

You may be charged fees for the services that the agency must perform when processing your request for public records, including fees for making photocopies and other lawful fees. **The first $30 of fees charged for searching for a record, reviewing, and segregating will not be charged to you. Any amount over $30 will be charged to you.** Fees are as follows:

Search for a Record	$2.50 for 15 minutes
Review and Segregation of a Record	$5.00 for 15 minutes

Generally, no search, review, and segregation fees may be charged if you are making a request for personal records that are about you.

WAIVER OF FEES IN THE PUBLIC INTEREST

As an alternative to the $30 fee waiver (not in addition to), the agency may waive the first $60 of fees for searching for, reviewing and segregating records when the waiver would serve the public interest. If you wish to apply for a waiver of fees in the public interest, you must attach to this request a statement of facts, including your identity as the requester, to show how the waiver of fees would serve the public interest. The criteria for this waiver, found at section 2-71-32, Hawaii Administrative Rules, are

(1) The requested record pertains to the operations or activities of an agency;
(2) The record is not readily available in the public domain; and
(3) The requester has the primary intention and the actual ability to widely disseminate information from the government record to the public at large.

COSTS

The Agency may charge you any other lawful fees and the costs to copy and deliver your personal or public record request.

AGENCY RESPONSE TO YOUR REQUEST FOR ACCESS

The agency to which you addressed your request must respond within a set time period. The agency will normally respond to you within 10 business days from the date it receives your request; however, in ***extenuating circumstances,*** the agency must respond within 20 business days from the date of your request. If you have questions about the response time or the records being sought, you should first contact the agency and request to consult with the agency's UIPA contact person.

Please note that the Office of Information Practices (OIP) does not maintain the records of other agencies and a requester must seek records directly from the agency. If the agency denies or fails to respond to your written request for records or if you have other questions regarding compliance with the UIPA, then you may contact OIP at 808-586-1400, oip@hawaii.gov, or 250 South Hotel Street, Suite 107, Honolulu, Hawaii 96813.

REQUESTER'S RESPONSIBILITIES

You have certain responsibilities under section 2-71-16, Hawaii Administrative Rules, which include making arrangements to inspect and copy records, providing further clarification or description of the requested record as instructed by the agency's notice, and making a prepayment of fees and costs, if assessed. The rules and additional training materials are available online at **oip.hawaii.gov** or from OIP.

REQUEST FOR WIAVER OF FEES IN THE PUBLIC INTEREST

My name is Paul Achitoff, Managing Attorney for the Mid-Pacific office of Earthjustice. I request a waiver of fees in the public interest pursuant to section 2-71-32, Hawaii Administrative Rules, because:

(1) The requested records pertain to the operations or activities of the State of Hawaiʻi Department of Agriculture ("DOA").

(2) The requested records are not readily available in the public domain because are not available on DOA's website nor, to my knowledge, in any other publicly-accessible place.

(3) Earthjustice is a non-profit public interest law organization dedicated to defending the right of all people to a healthy environment. Earthjustice has the primary intention and actual ability to widely disseminate the requested information from the government records to the public at large.

REQUEST TO ACCESS A GOVERNMENT RECORD

This is a model form that may be used by a Requester to provide sufficient information for an agency to process a record request. Although the Requester is not required to use this form or to provide any personal information, the agency needs enough information to contact the Requester with questions about this request or to provide its response. This request may not be processed if the agency has insufficient information or is unable to contact the Requester.

DATE: March 23, 2016

TO: Agribusiness Development Corporation
Agency that Maintains the Government Record

State Office Tower
235 S. Beretania St.
Room 205
Honolulu, Hawaii 96813
Agency's Contact Information

FROM: Paul Achitoff
Requester's Name or Alias

Earthjustice
850 Richards Street, Suite 400
Honolulu, HI 96813
(808) 599-2436
Requester's Contact Information

AS THE REQUESTER, I WOULD LIKE THE FOLLOWING GOVERNMENT RECORD:

Describe the government record as specifically as possible so that it can be located. Try to provide a record name, subject matter, date, location, purpose, or names of persons to whom the record refers, or other information that could help the agency identify the record. A complete and accurate description of the requested government record will prevent delays in locating the record. Attach additional pages if needed.

Please provide a copy of any written material describing or documenting any Title VI compliance program(s) the Agribusiness Development Corporation has or is implementing to ensure that its actions do not involve discriminatory treatment and do not have discriminatory effects even when facially neutral, as described in Title VI of the Civil Rights Act of 1964, Title VI, 42 U.S.C. § 2000d et seq.

I WOULD LIKE: (Please check one or more of the options below, as applicable)

☐ **To inspect the government record**

X **A copy of the government record:** (Please check only one of the options below.) See the next page for information about fees and costs that you may be required to pay for agency services to process your record request. Note: Copying and transmission charges may also apply to certain options.

☐ Pick up at agency (**date and time**):
☐ Mail (address): ______
X E-mail (address): achitoff@earthjustice.org
☐ Fax (toll free and only if available; provide fax number): ______
☐ Other, if available (please specify): ______

EXHIBIT 4

X If the agency maintains the records in a form <u>other than paper</u>, please advise in which **format you would prefer to have the record**.

X Electronic ☐ Audio ☐ Other (please specify):____________________

X Check this box **if you are attaching a request for waiver of fees in the public interest** (See waiver information on next page).

FEES FOR PROCESSING PUBLIC RECORD REQUESTS

You may be charged fees for the services that the agency must perform when processing your request for public records, including fees for making photocopies and other lawful fees. **The first $30 of fees charged for searching for a record, reviewing, and segregating will not be charged to you. Any amount over $30 will be charged to you.** Fees are as follows:

Search for a Record	$2.50 for 15 minutes
Review and Segregation of a Record	$5.00 for 15 minutes

Generally, no search, review, and segregation fees may be charged if you are making a request for personal records that are about you.

WAIVER OF FEES IN THE PUBLIC INTEREST

As an <u>alternative</u> to the $30 fee waiver (not in addition to), the agency may waive the first $60 of fees for searching for, reviewing and segregating records when the waiver would serve the public interest. If you wish to apply for a waiver of fees in the public interest, you must attach to this request a statement of facts, including your identity as the requester, to show how the waiver of fees would serve the public interest. The criteria for this waiver, found at section 2-71-32, Hawaii Administrative Rules, are

(1) The requested record pertains to the operations or activities of an agency;
(2) The record is not readily available in the public domain; and
(3) The requester has the primary intention and the actual ability to widely disseminate information from the government record to the public at large.

COSTS

The Agency may charge you any other lawful fees and the costs to copy and deliver your personal or public record request.

AGENCY RESPONSE TO YOUR REQUEST FOR ACCESS

The agency to which you addressed your request must respond within a set time period. The agency will normally respond to you within 10 business days from the date it receives your request; however, in ***extenuating circumstances,*** the agency must respond within 20 business days from the date of your request. If you have questions about the response time or the records being sought, you should first contact the agency and request to consult with the agency's UIPA contact person.

Please note that the Office of Information Practices (OIP) does not maintain the records of other agencies and a requester must seek records directly from the agency. If the agency denies or fails to respond to your written request for records or if you have other questions regarding compliance with the UIPA, then you may contact OIP at 808-586-1400, <u>oip@hawaii.gov</u>, or 250 South Hotel Street, Suite 107, Honolulu, Hawaii 96813.

REQUESTER'S RESPONSIBILITIES

You have certain responsibilities under section 2-71-16, Hawaii Administrative Rules, which include making arrangements to inspect and copy records, providing further clarification or description of the requested record as instructed by the agency's notice, and making a prepayment of fees and costs, if assessed. The rules and additional training materials are available online at **oip.hawaii.gov** or from OIP.

REQUEST FOR WIAVER OF FEES IN THE PUBLIC INTEREST

My name is Paul Achitoff, Managing Attorney for the Mid-Pacific office of Earthjustice. I request a waiver of fees in the public interest pursuant to section 2-71-32, Hawaii Administrative Rules, because:

(1) The requested records pertain to the operations or activities of the Agribusiness Development Corporation ("ADC").

(2) The requested records are not readily available in the public domain because are not available on ADC's website nor, to my knowledge, in any other publicly-accessible place.

(3) Earthjustice is a non-profit public interest law organization dedicated to defending the right of all people to a healthy environment. Earthjustice has the primary intention and actual ability to widely disseminate the requested information from the government records to the public at large.

DAVID Y. IGE
Governor

SHAN S. TSUTSUI
Lt. Governor

JAMES J. NAKATANI
Executive Director

STATE OF HAWAII
AGRIBUSINESS DEVELOPMENT CORPORATION
235 S. Beretania Street, Room 205
Honolulu, HI 96813
Phone: (808) 586-0186 Fax: (808) 586-0189

March 30, 2016

Mr. Paul Achitoff
Earthjustice
850 Richards Street, Suite 400
Honolulu, Hawaii 96813

Dear Mr. Achitoff:

This in response to your Request to Access a Government Record dated March 23, 2016. The Agribusiness Development Corporation (ADC) does not have any Title VI compliance programs, and therefore has no document responsive to this request. If you are thinking of a particular ADC document, please identify the document, and the ADC can search for it further.

If you have any further questions, please call me at 586-0186.

Thank you.

Sincerely,

James J. Nakatani
Executive Director

EXHIBIT 5

Paul Achitoff

From:	Yee, Bryan C <bryan.c.yee@hawaii.gov>
Sent:	Wednesday, April 27, 2016 5:21 PM
To:	Paul Achitoff
Subject:	RE: UIPA Request to the Department of Agriculture
Attachments:	0601001 Discrimination Harassment Free Workplace Policy.pdf; hdoa limited english proficiency plan.pdf

The Hawaii Department of Agriculture (HDOA) referred your UIPA request to me for a response. I have attached two documents which HDOA identified may be relevant to your UIPA request. The first is Policy No. 601.001 entitled "Discrimination/Harassment-Free Workplace Policy." The second is the Department of Agriculture's Limited English Proficiency Plan.

HDOA does not have a document specifically described as HDOA Title VI program. So, we have tried our best to identify the documents relevant to your request. Pursuant to our phone call, I have not included copies of the standard contract provision requiring all contractors to comply with local, State, and federal laws or with the standard grant provision similarly requiring compliance with all federal laws.

If you have any questions, feel free to either email me or call me at 586-1180. Thank you.

EXHIBIT 6

	STATE OF HAWAII DEPARTMENT OF HUMAN RESOURCES DEVELOPMENT **POLICIES AND PROCEDURES**	POLICY NO. 601.001	NO. of PAGES 7 2 Attachments
		EFF. DATE October 15, 2013	REV.NO./Date N/A
TITLE:	**DISCRIMINATION/HARASSMENT-FREE WORKPLACE POLICY**	APPROVED: Barbara A. Krieg, Director	

I. POLICY

The State and its appointing authorities are committed to promoting and maintaining a productive work environment free of any form of discrimination, harassment and retaliation. The State and its appointing authorities do not tolerate workplace discrimination, harassment or retaliation. The State and its appointing authorities are required to and will take appropriate action when discrimination, harassment or retaliation is based on a person's protected class.

The State and its appointing authorities will act to curb protected class discrimination or harassment without regard to its severity or pervasiveness and does not require that discrimination or harassment rise to the level of unlawfulness before taking action. Every State employee is responsible for assuring that work in the executive branch is conducted in an atmosphere that respects the dignity of every State employee, and people with whom the State conducts business. State employees are expected to avoid behavior that could reasonably be perceived as discrimination or harassment prohibited under this policy. In addition, State employees are expected to avoid retaliation against an individual who makes a complaint, and/or participates in or provides information for an investigation relating to discrimination and/or harassment. A violation of this policy may result in disciplinary action, up to and including termination, in accordance with applicable State laws, rules, policies, and collective bargaining agreements.

The State and its appointing authorities will also make reasonable accommodations, if needed, to the extent required by law, for employees who are disabled, pregnant (including pregnancy-related disabilities), breastfeeding, victims of sexual or domestic abuse, or for bona fide religious purposes. Any employee who believes he/she needs accommodation for any of these reasons should contact his/her manager, Departmental Personnel Officer (or his/her designee), Departmental EEO or Civil Rights Compliance Officer, or the Executive Branch Equal Employment Opportunity Office (587-1162 or eeo@hawaii.gov).

II. PURPOSE

The purpose of this policy is to assure compliance with all federal and State laws and to prevent discrimination, harassment, and retaliation in the workplace.

EXHIBIT 7

This policy is intended to protect all applicants, employees, and individuals providing services to the State on a non-paid basis (e.g. volunteers or interns) from discriminatory or harassing conduct by employees or non-employees and to prevent employees from engaging in discriminatory or harassing conduct directed to any individual (whether employees or non-employees).

III. DEFINITIONS

"Gender identity or expression" includes a person's actual or perceived gender, as well as a person's gender identity, gender-related self-image, gender-related appearance, or gender-related expression, regardless of whether that gender identity, gender-related self-image, gender-related appearance, or gender-related expression is different from that traditionally associated with the person's sex at birth.

"Genetic information" includes information about an individual's genetic tests and the genetic tests of an individual's family members, as well as information about any disease, disorder, or condition of an individual's family members (i.e. an individual's family medical history). Family medical history is included in the definition of genetic information because it is often used to determine whether someone has an increased risk of getting a disease, disorder, or condition in the future.

"Protected class" means race, color, sex, including gender identity or expression, sexual orientation, condition of pregnancy, act of breastfeeding or expressing milk, religion, national origin, ancestry, age, disability, genetic information, marital or civil union status, arrest and court record (except as permitted by applicable laws), income assignment for child support, national guard absence, uniformed service, veteran status, citizenship (except as permitted by applicable laws), credit history or credit report (unless directly related to a bona fide occupational qualification), domestic or sexual violence victim status if the domestic or sexual violence victim provides notice to the victim's employer of such status or the employer has actual knowledge of such status, or any other classification protected under applicable state or federal laws.

"Protected class discrimination or harassment" means any unwelcome behavior based on a person's protected class which is sufficiently severe or pervasive and has the purpose or effect of either unreasonably interfering with the person's work performance or creating an intimidating, hostile, or offensive work environment.

"Retaliation" means an adverse action taken or threat of adverse action in response to or in an attempt to prevent an individual from opposing a discriminatory practice or from participating in an employment discrimination investigation or proceeding.

IV. SCOPE

This policy applies to all employees and applicants in the executive branch under the jurisdiction of the Department of Human Resources Development, whether civil service or exempt employees, full-time or part-time employees, permanent or temporary employees.

V. PROHIBITED CONDUCT

A. It is a violation of this policy to engage in protected class discrimination or harassment.

1. Protected class characteristics may not be used as a basis for taking employment action or making an employment decision that results in a significant change in benefits, or terms and conditions of employment.

2. Harassing or offensive conduct directed at individuals based on protected class characteristics is prohibited under this policy, and includes, but is not limited to:

   a. Unwanted physical contact, sexually suggestive or offensive touching, patting, hugging, or brushing against a person's clothing or body, pinching, or hitting;

   b. Sexual advances, requests for sexual favors, repeated and unwanted attempts at a romantic relationship, sexually explicit questions, comments about physical attributes;

   c. Lewd descriptions, sexual jokes, pressure for sexual activity, such as repeated requests for dates, and threats for refusing a sexual advance;

   d. Displays of demeaning, insulting, objects, pictures, or photographs relating to any protected class;

   e. Demeaning, insulting, intimidating, written, recorded, or electronically transmitted messages (such as email, text messages, voicemail, and Internet materials) relating to any protected class;

   f. Derogatory comments, slurs, jokes, profanity, anecdotes, and/or offensive questions based on or directed at any protected class; and/or

g. Any employment action or decision that adversely impacts a protected class of employees or applicants.

B. Retaliation against an individual who makes a complaint, participates in an investigation, or provides information related to any complaint, is prohibited. Retaliation includes, but is not limited to, any adverse action taken or threat of adverse action in response to any of the following actions or any attempt to prevent an individual from taking any of the following actions:

1. Making a complaint of harassment or discrimination;
2. Making a request for reasonable accommodation;
3. Participating in a complaint investigation or proceeding; or
4. Otherwise opposing acts of discrimination.

VI. PROCEDURES

A. REPORTING PROCEDURES

1. The State and its appointing authorities encourage employees to report discrimination, harassment, and/or retaliation, regardless of the identity of the alleged offender or whether the offender is an employee of the executive branch, before it becomes severe or pervasive so that steps may be taken to stop the offending behavior before it rises to the level of unlawful behavior.
2. Conduct that violates the Discrimination/Harassment-Free Workplace Policy should be reported to the employee's manager, the Departmental Personnel Officer (or his/her designee), the Departmental EEO or Civil Rights Compliance Officer, or the Executive Branch Equal Employment Opportunity Office (587-1162 or eeo@hawaii.gov).
3. Anyone who observes or experiences discrimination, harassment or retaliation prohibited under this policy is encouraged, if at all possible, to make it clear to the offender that he or she finds such behavior offensive. **Employees are not required, however, to make a complaint to the offender.**
4. A complaint or report may be made either orally or in writing, using the Discrimination Complaint Form (see Attachment A). A complaint or report, whether oral or written, should include:

name of the alleged offender(s), including position and department, if known, a summary of the offensive acts, the dates, times and places of the incidents, the names of witnesses to the events, and copies of documents, if any, that support the complaint or report.

B. CONFIDENTIALITY

The State and its appointing authorities will take appropriate steps to protect the confidentiality of discrimination, harassment and retaliation complaints, investigations, and reports, whether substantiated or unsubstantiated. However, complete confidentiality cannot be guaranteed and information regarding complaints, investigations and reports shall be shared with appropriate individuals and agencies on a "need to know" basis, with due consideration for the safety and security of individuals involved in the investigation.

C. RESPONSIBILITIES

1. Department Responsibilities

   a. In alignment with this Discrimination/Harassment-Free Workplace Policy, department or agency heads are responsible for developing and enforcing their own discrimination/harassment free workplace investigation and enforcement processes within their own departments or agencies.

   b. Should a conflict exist, this Discrimination/Harassment-Free Workplace Policy shall take precedence over all policies and/or procedures that are developed by the departments or agencies.

   c. Departments are responsible for distributing this Discrimination/Harassment-Free Workplace Policy to all of its employees using the Discrimination/Harassment-Free Workplace Policy Acknowledgment Form (see Attachment B).

   d. Departments shall forward a copy of any and all complaints of discrimination, harassment or retaliation, whether made internally or to the Equal Employment Opportunity Commission or Hawaii Civil Rights Commission, to designated persons within their department or agency and, in addition, to the Executive Branch Equal Employment Opportunity Office.

e. Departments are responsible for making sure all complaints are investigated promptly. Departments may take appropriate interim action while an investigation is pending, including placing an accused person on leave or temporarily in another position.

f. If the Department finds that an employee violated the Discrimination/Harassment-Free Workplace Policy, the Department will take appropriate corrective action, up to and including termination of the employee, in accordance with applicable State laws, rules, policies, and collective bargaining agreements. If the person found to have violated the policy is not employed by the State or its appointing authorities, other appropriate action shall be taken, including notice to the actual employer.

2. Managers' and Supervisors' Responsibilities

a. Managers and supervisors are responsible for maintaining a workplace free of harassment, discrimination and retaliation. Managers and supervisors who witness or receive reports of offending action shall take immediate and appropriate action to ensure any wrongful behavior ceases, and shall forward all such reports to the designated persons within their department.

b. Managers and supervisors, as assigned within their departments, shall investigate complaints of alleged violations of this Policy in a fair and impartial manner.

3. Employee Responsibilities

a. Employees are expected to conduct themselves appropriately while at work and during work-related functions and refrain from any acts of discrimination, harassment or retaliation.

b. Employees who experience or observe any unlawful harassment, discrimination or retaliation, have a duty and responsibility to report the incident(s) in order to correct and prevent unlawful harassment, discrimination or retaliation.

D. REFERRING COMPLAINTS TO EXTERNAL AGENCIES

1. In addition to the procedures described above, employees may make complaints about discrimination, harassment, or retaliation in the workplace to other appropriate agencies, including but not limited to, the federal Equal Employment Opportunity Commission (www.eeoc.gov) and the Hawai'i Civil Rights Commission (http://labor.hawaii.gov/hcrc).

2. Employees wishing to file complaints with other agencies should contact that agency to obtain information on their specific procedures and should not wait for resolution of a complaint made to the employer. Agencies may have time limitations for filing complaints. For example, complaints of unlawful discriminatory practices must be filed with the Hawai'i Civil Rights Commission no later than one hundred eighty (180) days, or with the Equal Employment Opportunity Commission no later than three hundred (300) days from the date: (1) the alleged unlawful discriminatory act occurred; or (2) the last occurrence in a pattern of ongoing discriminatory conduct.

VII. AUTHORITIES AND REFERENCES

Title VII of the Civil Rights Act of 1964 as amended

The Pregnancy Discrimination Act

The Age Discrimination in Employment Act of 1967

The Equal Pay Act of 1963

Titles I and II of the Americans with Disabilities Act of 1990 as amended

Sections 102 and 103 of the Civil Rights Act of 1991

Sections 503 and 504 of the Rehabilitation Act of 1973

The Genetic Information Nondiscrimination Act of 2008

The Immigration Reform and Control Act of 1986

Chapter 378, Hawaii Revised Statutes

VIII. ATTACHMENTS

Attachment A: Discrimination Complaint Form, HRD Form 613

Attachment B: Discrimination/Harassment-Free Workplace Policy Acknowledgment Form

NEIL ABERCROMBIE
Governor

RUSSELL S. KOKUBUN
Chairperson, Board of Agriculture

SCOTT E. ENRIGHT
Deputy to the Chairperson

State of Hawaii
DEPARTMENT OF AGRICULTURE
1428 South King Street
Honolulu, Hawaii 96814-2512

DEPARTMENT OF AGRICULTURE
LIMITED ENGLISH PROFICIENCY PLAN

PURPOSE OF PLAN

Effective immediately, this Department of Agriculture Limited English Proficiency Plan shall be implemented to ensure that the Hawaii Department of Agriculture ("HDOA") provides language accessible services to limited English proficient individuals or organizations accessing, participating or benefiting from services, programs and activities offered by the department in order to meet the requirements of Act 290, SLH 2006, codified into Part II of Chapter 371, HRS, and Presidential Executive Order 13166.

BACKGROUND

Presidential Executive Order 13166, "Improving Access to Services for Persons with Limited English proficiency" was created to ". . . improve access to . . . federally assisted programs and activities for persons, who as a result of national origin, are limited in their English proficiency . . . ." Title VI of the Civil Rights Act of 1964, 42 U.S.C. § 2000d ("Title VI") serves as the basis for Executive Order 13166. Title VI provides that no person shall "on the ground of race, color, or national origin, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance." Certain divisions of the HDOA receive Federal funding and, by virtue of that funding, Title VI applies to all HDOA's operations. *See* 29 CFR parts 31.1; 31.2(g); and 31.3. Accordingly, HDOA seeks to implement the initiatives set forth in this Limited English Proficiency ("LEP") Plan to meet its obligations under Title VI. The purpose of this LEP Plan is to take reasonable steps to ensure persons with limited English proficiency gain meaningful access to HDOA services and programs.

Hawai`i's population reflects a rich blend of peoples and cultures. According to the 2000 census, almost 290,000 of Hawai`i's 1.2 million people speak a language other than English at home, including over 250,000 persons that speak an Asian or Pacific Island language. For many, English is not their primary language. Many have only a limited ability to read, write, speak or understand English. Language barriers often prohibit many residents from fully participating in our community and undermine efforts to become self-sufficient and productive. This LEP Plan speaks to HDOA's commitment to provide essential and meaningful access to LEP customers.

DEFINITION OF LIMITED ENGLISH PROFICIENT PERSONS/CUSTOMERS

For purposes of this LEP Plan, LEP persons or LEP customers mean individuals who do not speak English as their primary language and who have a limited ability to read, write, speak, or understand English. Such persons may be eligible to receive language assistance with respect to a particular service, benefit, or encounter.

EXHIBIT 8

RELEVANT FACTORS

In determining how to provide effective and meaningful access to LEP customers, the U.S. Department of Labor has established the following four guidelines (68 FR 32290, 32294 (May 29, 2003)):

1. The number or proportion of LEP persons eligible to be served or likely to be encountered by the program;

2. The frequency with which LEP persons come into contact with the program;

3. The nature and importance of the program, activity, or service provided by the program to LEP persons; and

4. The resources available to the program and the costs of providing interpretation/translation services.

The touchstone of this four-factor analysis is reasonableness--reasonableness as measured by balancing (1) the size, needs, and the nature of assistance to the LEP population served and (2) HDOA's capacity and available resources.

SUMMARY

This HDOA LEP Plan is comprised of six (6) components:

(1) Designation of Responsibilities;

(2) Development of a reporting system designed to obtain key information about the LEP Customers who use HDOA services;

(3) Compilation of comprehensive multi-lingual listing of HDOA employees;

(4) Notice of interpretation/translation services to qualified LEP customers;

(5) Providing interpretation/translation services for qualified LEP customers;

(6) Seek stakeholders' input; review and revision of the LEP Plan.

Each component will be explained below.

LEP PLAN

I. DESIGNATION OF RESPONSIBILITIES

Chairperson

The Chairperson shall designate a person to serve as the LEP Plan Coordinator.

LEP Plan Coordinator

The LEP Coordinator shall be responsible to:

(1) coordinate, monitor, and evaluate the overall implementation of the LEP Plan;
(2) coordinate responses to any inquires or comments/complaints regarding the LEP Plan and its implementation;
(3) coordinate any revisions and modifications to the LEP Plan, as necessary;
(4) train HDOA division and program managers, by providing the proper background necessary to implement the objectives of the LEP Plan;
(5) coordinate efforts to solicit stakeholders' input aimed at improving the current LEP Plan;
(6) coordinate the compilation of the listing of materials/documents that should be translated from English into a foreign language;
(7) develop a survey form to collect information necessary to enable the department to render meaningful access to its LEP customers and compile the data on a yearly basis and submit an annual report to the Chairperson and Deputy by no later than July 31, 2008 and every year at this date thereafter;
(8) compile listing of multi-lingual listing of HDOA employees who would be willing to provide interpretation/translation services to LEP customers; and
(9) compile listing of interpreters/translators and their costs for program personnel to use in providing services to their LEP customers.

Division Administrators and Program Managers

The Division Administrators and Program Managers shall be responsible to:
(1) identify and determine important materials/documents that should be translated from English into a foreign language;
(2) compile information requested by the LEP Plan Coordinator on multi-lingual HDOA employees and LEP customers;
(3) ensure appropriate program staff have reviewed and been trained on implementing the LEP Plan including the proper background necessary to implement the objectives of the LEP Plan;
(4) inform what LEP interpretation/translation services are available to their customers;
(5) respond to request for oral and written translation services by identifying available internal bi-lingual staff or contacting available interpreter services and record information about oral or written language service provided;
(6) monitor program staff to ensure that the LEP Plan is being implemented; and
(7) notify the LEP Coordinator of any complaints/concerns from customers regarding LEP services provided by the department.

Employees

Each employee is responsible to:
(1) review and assist in the implementation of the LEP Plan;
(2) assist in obtaining interpretation/translation services for LEP customers and record information about oral or written language service provided, if applicable; and
(3) notify division administrator or program manager of any complaints/concerns from customers regarding LEP services provided by the department.

II. DEVELOPMENT OF A REPORTING SYSTEM TO OBTAIN KEY INFORMATION ABOUT THE LEP CUSTOMERS WHO USE HDOA SERVICES

In order to provide meaningful access to LEP customers, HDOA has gathered information about what languages they speak. HDOA will determine what services they use, and the frequency with which they use these services.

In July 2006, the Hawaii Agricultural Statistical Service, a branch of the HDOA, conducted a language study of Hawaii agricultural workers (see attachment A). This study identified the first language of workers and operators (farm/ranch owners) as well as their level of English and math proficiency. These statistics, however, are limited to the types of languages spoken and do not reflect the kinds of HDOA services requested or provided or how frequently such services were used by LEP customers.

The study showed the most prevalent first language among Hawaii agricultural workers is Ilocano at 2,560 or 40 percent of the total estimate of 6,410. The second most prevalent language among Hawaii agricultural workers is English, estimated at 2,280 or 36 percent.

Of those workers whose first language is Ilocano, 2,040 or 80 percent understand written instructions in their first language. Of the same population, 2,270 or 89 percent comprehend English verbal instructions and 1,520 or 59 percent comprehend English written instructions.

Hawaii agricultural operators' first language is predominantly English, at 2,730 or 88 percent of the total estimate of 3,090.

A survey form designed to collect the information necessary to enable us to render meaningful access to LEP customers who use our services was developed. This form will be filled out by all appropriate HDOA employees and collect, among other things, the following information: (1) the kinds of HDOA services requested by LEP customers; and (2) the frequency with which LEP customers use certain HDOA services. The data will be compiled on a yearly basis and an annual report prepared and submitted to the Chairperson and Deputy no later than July 31, 2008 and every year at this date thereafter. HDOA will use this information to develop the appropriate set of services.

III. COMPILATION OF COMPREHENSIVE MULTI-LINGUAL LISTING OF HDOA EMPLOYEES

To effectively service LEP customers, HDOA must ascertain what language skills and resources it may already have available through its employees.

HDOA has compiled information volunteered by HDOA personnel including, among other things, the language or languages that the HDOA employee can speak and/or read, the degree of fluency in those identified languages, and the contact information for that HDOA employee. An employee on this list may be contacted when a LEP customer requesting HDOA services needs language assistance.

HDOA has identify external organizations and individuals that have language capabilities that can be called upon for assistance. In the past, HDOA has worked with Pacific Gateway and University of Hawaii College of Tropical Agriculture and Human Resources (UHCTAHR) as well as individuals throughout the islands with diverse language expertise.

Pursuant to HRS Section 371-33(d), to the extent that HDOA requires additional personnel to provide oral and written language services as determined by the totality of the circumstances and relevant factors in HRS Sections 371-33(a)(1)-(4), HDOA will hire qualified personnel who are bilingual to fill existing, budgeted vacant public contact positions.

IV. NOTICE OF INTERPRETATION/TRANSLATION SERVICES TO LEP CUSTOMERS

A. OFFICE NOTICE

The HDOA employee will inform LEP customers orally, as required when reasoned or recognized, of the availability of an oral interpreter/translator in their primary language. Signage developed by the Office of Language Access and adapted for HDOA, will be posted and invite LEP customers to indicate they are in need of oral language services.

B. REQUESTING WRITTEN TRANSLATION

The HDOA employee will inform LEP customers in person and over the phone, as required when reasoned or recognized, of written translation services available. Should the LEP customer request written translation services, the employee shall notify the Program Manager or Division Administrator who shall respond to the request.

V. PROVIDING INTERPRETATION/TRANSLATION SERVICES FOR LEP CUSTOMERS

A. ORAL INTERPRETATION

If an individual approaches a HDOA employee and appears to be accessing services but has difficulty communicating what he or she needs, the employee shall respond as follows:

(1) When a request for an interpreter is made either orally or in writing, the employee shall determine whether bi-lingual staff in the office or a nearby unit is available who speaks the language being requested. The employee shall record information on the interpreter services provided on Attachment C.

(2) When bilingual staff is not available, the employee shall refer the request to their Program Manager or Division Administrator. The Program Manager or Division Administrator shall contact Pacific Gateway at 845-3918 or the appropriate department personnel of the University of Hawaii, College of Tropical Agriculture and Human Resources (UHCTAHR) specializing in the area of inquiry to request interpreter services. The Program Manager or Division Administrator shall record information on the interpreter services provided on Attachment C. The program or division shall be responsible to cover any cost related to providing the interpreter services.

(3) In the event an individual declines the offer to be provided a free interpreter, the individual should be asked to sign a waiver (Attachment D). The waiver should be kept in the client's file.

B. WRITTEN TRANSLATION

In 2007, the HDOA conducted an internal assessment and contacted the Hawaii Farm Bureau Federation in order to find out the need for interpretation or translation services. The HDOA subsequently compiled a listing of material and documents identified and determined by the division and/or program managers as important and/or believed to be important through the experiences of the program, and needing translation from English into a foreign language.

The HDOA currently has five (5) documents translated into various languages. The HDOA will continue to consult with its Administrators and Managers to determine whether any additional materials need clarification and translation. Written translations of documents are subject to the four-factor analysis and reasonableness. Examples of translated materials are included as Attachment B. (NOTE: For booklets, only the cover of the respective document is attached)

For LEP groups that meet the 5% threshold but number less than 50, the HDOA will determine whether to provide written notices on important documents notifying the individual of their right to receive competent oral interpretation of written materials in their primary language.

VI. SEEK STAKEHOLDERS' INPUT; REVIEW AND REVISION OF THE LEP PLAN

HDOA will actively seek input from agricultural organizations that have contact with LEP customers.

This LEP Plan shall be reviewed and revised periodically in light of comments from LEP customers, their representatives, interested stakeholders, and HDOA staff.

An updated LEP Plan shall be submitted to the Office of Language Access by July 1, 2013 and every two (2) years thereafter.

CONCLUSION

Through the enactment of this LEP Plan, HDOA, in compliance with the mandate of Title VI, has memorialized the initial steps in providing reasonable and meaningful access to LEP customers that seek HDOA services.

All HDOA divisions and administratively attached agencies shall immediately comply with this LEP plan.

Date: July 1, 2013

Attachments

Attachment A - Language Study of Hawaii Agricultural Workers

Attachment B - Examples of HDOA Translated Materials *

Attachment C - Limited English Proficiency Translation Services Monthly Log

Attachment D – Waiver of Interpreter Services

* For booklets, only the cover of the respective document is attached

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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF HAWAI'I

SYNGENTA SEEDS, *et al.*, *Plaintiffs*, v. COUNTY OF KAUA'I, *Defendant*, and KA MAKANI HO'OPONO, CENTER FOR FOOD SAFETY, PESTICIDE ACTION NETWORK NORTH AMERICA, and SURFRIDER FOUNDATION *Proposed Intervenor-Defendants*.	Case No.: 14-cv-00014-BMK **DECLARATION OF HOWARD HURST IN SUPPORT OF KA MAKANI HO'OPONO, CENTER FOR FOOD SAFETY, PESTICIDE ACTION NETWORK NORTH AMERICA, AND SURFRIDER FOUNDATION'S MOTION TO INTERVENE**

EXHIBIT 9

DECLARATION OF HOWARD HURST

1. I am over the age of 18 and have personal knowledge of the statements in this declaration.

2. I have been a volunteer member with Pesticide Action Network North America ("PANNA") and volunteer project director of the ad hoc coalition Maluhia Group (Hawai'i) since the fall of 2006. Maluhia Group is a coalition of Waimea Canyon Middle School staff, parents and community members concerned with the use of pesticide, and the agriculture of genetically engineered (GE) crops on lands adjacent WCMS campus. Based upon my personal knowledge and experience and based upon my education and profession, I am very concerned about the effects of pesticides on my health, children in my school, and on teachers.

3. I am a teacher in Waimea, Hawai'i 96796. I have been a teacher at Waimea Canyon Middle School for over 17 years. I hold a Master of Science degree in the physiology of learning disabilities from Brooklyn College, graduating magna cum laude. As a Special Education English teacher, I work with children with learning disabilities 10 to 14 years of age. Waimea Canyon Middle School is bounded by Syngenta's genetically engineered seed facility, which includes experimental testing fields next to the school. The distance from the nearest

classroom to agricultural lands applied with pesticides is approximately 100 yards. These agricultural lands are windward of the school.

4. The fields adjacent to and near the school are sprayed with pesticides regularly throughout the year, but especially in fall and winter when school is in session. There are also prevailing coastal winds that move across the fields towards the school daily. Syngenta acknowledged the pesticide sprayed in one incident in 2008 was the insecticide lambda-cyhalothrin, which the European Union considers a "suspected endocrine disruptor." In their study, the University of Hawaii passively sampled and found evidence of the neurotoxicant pesticide chlorpyrifos in 2011 and 2012. Maluhia Group members and I worked with PANNA scientists collecting air samples and found evidence of the chemical ethalfluralin in 2011. Because none of these pesticides are applied at or by the school, all likely drifted away from the Syngenta application sites onto school grounds.

5. Students and staff have regularly reported unsettling, chemical fuel-like smells, coinciding immediately or shortly after pesticides were applied on agricultural lands windward of the school.

6. In November 2006, after school staff including myself witnessed an application of pesticides by Syngenta on the adjacent fields, over 60 students reported to the health room complaining of severe headache, nausea, disorientation, and "flu-like" symptoms. Multiple classes of middle school children

were relocated to the only building with air conditioning in an effort to avoid the noxious fumes. Many students had to return to their classrooms due to space constraints in the Health Room. I did my best to treat my student's itchy eyes, dizziness, and nausea. Teachers, concerned about the number of incidents like this and worried about the health implications for the whole school, contacted Hawaii State Teacher's Association Representative Tom Perry who immediately came to the campus. After witnessing the continuing field operations and experiencing firsthand the symptoms being reported by students and staff, Tom Perry called 911 and the Kauai Fire Department that same day. Ten students were taken to Kauai Veterans Memorial Hospital. Some other teachers filed workers compensation claims and many transferred to different schools or left the island. Of the 36 teachers hired since the first incident at Waimea Canyon Middle School, 23 have left the school. My General Practitioner documented my symptoms of headache, muscle ache, malaise, labored breathing, itchy eyes, nausea, as "possible pesticide poisoning." The Department of Agriculture (DOA) focused the blame on "stink weed" plants, but the symptoms exhibited were consistent with pesticide poisoning and identified on the known applied pesticide labels and Material Safety Data Sheets by a wide spectrum of people, not common allergies among allergy-sufferers.

7. On January 1, 2008, 72 students were documented as having inhaled a noxious odor that resulted in dizziness, headache, malaise, red itchy eyes and nausea, with 12 of the students having severe enough symptoms to be taken to the hospital. After a Freedom of Information request the local newspaper The Garden Island counted numerous other students that weren't included in the officially-documented number. The school's administration called the Kauai Fire Department and soon after, representatives from the Hazardous Materials Assessment and Response Division, Department of Health, DOA, Hawaii State Teachers Association, and the Department of Education were on site. T- Building, the classroom building closest to Syngenta agricultural land, was evacuated and an investigation ensued. Syngenta claims, like it has in other incidents, that the effects were due to the local "stinkweed." Unfortunately, the DOA initially agreed with these claims, but then a follow-up DOA study found that impacts from the benign weed Cleome gynandra or "stinkweed" were insignificant. Similar levels of Cleome gynandra were found at all school control sites as well as WCMS and there were no incidents at these control sites attributed to "stinkweed."

8. After receiving an e-mail from the principal that Syngenta was going to spray a neighboring field with chlorpyrifos in 2008, I joined teachers as we picketed outside the school and, with the assistance of the Hawaii State Teachers Association, successfully forced Syngenta to, at a minimum, cease operations on

field #809, the field closest to school classrooms. The Hawaii State Teachers' Association brought suit and a Kauai court issued a temporary restraining order requiring Syngenta to cease operations on field #809. Following the restraining order (which has since expired), the Teachers Association was able to elicit a voluntary agreement from Syngenta to abandon agricultural operations in field #809 only. Operations continue in all other fields in the area.

9. As a volunteer with PANNA, I have been involved in air quality monitoring for pesticides in the air near our middle school, finding positive results. In January 2011, Maluhia group member, PANNA volunteer and certified Drift Catcher trainer Matthew Snowden actively sampled for and found the herbicide ethalfluralin, a pesticide EPA considers a possible carcinogen, during a 3-day period (1/7/11-1/9/11). The Drift Catcher, which found ethalfluralin, was placed on the property line of the home immediately adjacent to the North edge of the school.

10. The University of Hawai'i's "Air Sampling and Analysis for Pesticide Residues and Odorous Chemicals in and Around Waimea, Kauai," commissioned by the DOA and County of Kaua'i, resulted in positive findings of chlorpyrifos at Waimea Canyon Middle School during three periods over a year: 6/6/11-10/12/11, 10/12/11-2/12/12, and 2/12/12-6/11/12. Due to the flawed nature of this form of passive sampling, the study can only report that chlorpyrifos was detected at all sites tested during each of the three periods (2 indoor sites and 2

outdoor sites). In addition, researchers also used high volume active sampling during the short period 2/10/12-2/18/12, and found chlorpyrifos at levels considered to be unhealthy for children. During the period of time covered by the University of Hawai'i study, there were multiple incidents of illness "spikes" unlike predictable student illness patterns, with symptoms such as itchy eyes, dizziness, nausea, headache which are all indicative of pesticide exposure. Fortunately, there were no evacuations during the time of the study, but this is likely due to altered spray patterns by Syngenta during the study and not spraying the entire week the high-volume sampler was running. Many parents that signed their children out of school during these "spikes" reported that the symptoms dissipated shortly after leaving the drift area (Waimea Canyon Middle School campus).

11. The concerns from the past several years are not limited to Waimea Canyon Middle School. For example, I am personally aware of a similar drift incident at Kekaha School in 2008, approximately 3 miles from Waimea Canyon Middle School. Both schools bookend Syngenta's genetically engineered seed testing lands. DOA reports have consistently failed to adequately test for drift and have been therefore unable to document harm.

12. Syngenta continues agricultural pesticide application operations on fields within one-quarter mile of Waimea Canyon Middle School and "spikes" of

illness symptoms indicative of pesticide exposure (that is, the symptoms are the same as those described in the incidents above) occur on days when there is active field spraying and the winds are from that direction. Although Syngenta has voluntarily ceased operations on field #809—the nearest field—and planted hedgerows, during spray season students and staff continue to experience symptoms indicative of chronic pesticide exposure. There have been no acute incidents since spraying ceased on field #809. Unfortunately, there is no biomonitoring or active air sampling going on to identify the current magnitude of the problem.

13. Through first person knowledge I'm aware that 11 of the 23 teachers leaving the school since the first drift incident have transferred from Waimea Canyon Middle School or left the island altogether due to health concerns associated with the pesticide applications by Syngenta. This represents almost half the staff of the school.

14. Despite the many incidents and evacuations little has changed; Syngenta is still spraying on the West side of Kaua'i. Prior to the passage of Bill 2491, there were no new buffer requirements except for a voluntary decision to stop spraying in a field closest to school classrooms, reached only after pesticide exposure to children and considerable pressure on Syngenta brought by teachers. Students and school staff, including myself, will continue to be injured by these

dangerous pesticides as they drift from neighboring fields, unless new policies are put in place.

15. I consider myself an educator and I have dedicated my life to assisting children in low-income communities. I support PANNA's efforts to defend, on behalf of its members, such as me, this lawsuit seeking to invalidate Bill 2491 (Ordinance 960), which requires the chemical companies, including Syngenta, to warn neighbors, such as me, of pesticide spraying, and disclose the chemicals being sprayed so affected people will not be forced to guess what they have been exposed to, or rely for help on State agencies that have demonstrated an inability or unwillingness to address the problem to protect schoolchildren, or me.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct. Executed this 17th day of February, 2014, at Waimea, Hawai'i.

HOWARD HURST

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION IX
75 Hawthorne Street
San Francisco, CA 94105

FEB 20 2013

VIA E-MAIL

Scott E. Enright
Deputy to the Chairperson
Hawaii Department of Agriculture
1428 South King Street
Honolulu, HI 96814

Dear Mr. Enright:

Enclosed is the Draft End-of-Year Evaluation Report of the FY12 Pesticide Performance Partnership Grant between the Hawaii Department of Agriculture (HDA) and the U.S. Environmental Protection Agency (EPA), Region 9.

The End-of-Year Report is based on the reports and documents that HDA provided to EPA as well as an on-site visit in November, 2012. Our review found that HDA continues to maintain a quality program and the Pesticide Program met all major outputs and projections for FY12. Inspection projections were exceeded, and several large-scale projects were completed, such as the Branch and Laboratory Standard Operating Procedures, and the Pesticide Quality Assurance Project Plan which was drafted and forwarded to EPA. Additional programmatic findings are located within the body of the report.

Please review the enclosed report and provide any comments or additions to Mary Grisier within 30 days. If no comments are received, the report will be considered final.

Sincerely,

Pamela Cooper

Pamela Cooper, Manager
Pesticides Office

Enclosure

Cc: Thomas Matsuda, HDA
Dean Yoshizu, HDA
Vernese Gholson, (MTS-7)
Mary Grisier, (CED-5)

EXHIBIT 10

U.S. Environmental Protection Agency
Hawaii Department of Agriculture
FY2012 End-of-Year Review

Pesticide Performance Partnership Grant

Executive Summary- This report covers workplan activities conducted in FY12, and is based on discussions and review of documents throughout the year and during the end of year visit. Discussions were held during the end of year visit that focused on recent changes to the pesticide program at Hawaii Department of Agriculture (HDA). Recommendations for improvements to inspection procedures can be found within the body of this report. This report covers the first year of a two-year performance partnership grant between Hawaii Department of Agriculture and EPA Region 9. This grant was put into place to ease administrative burdens on HDA and to allow for more long-term planning for the Pesticide program. Databases that track certified applicator education and licensing are in need of updating and integration. FY14 negotiations should include discussions of how this might be accomplished.

I. BACKGROUND

A. General

1. **Project Period:** October 1, 2011 – September 30, 2012.

2. **EPA Assistance Agreement Number:** #BGOOT64412

3. **Review method:** On-site

4. **Review participants:**

EPA: Mary Grisier, Hawaii Pesticide Project Officer Grantee: Thomas Matsuda, Pesticide Program Manager, Avis Onaga, Case Preparation Officer, and Dean Yoshizu, Compliance Officer

5. **Review date(s) and location:** November 8-10, 2012 at the Hawaii Department of Agriculture offices in Honolulu.

B. Scope of Review

The Hawaii Department of Agriculture (HDA) has partial primary enforcement responsibility over pesticide use activities in the State of Hawaii and is the lead state agency for the enforcement of the Hawaii Pesticides Law (Chapter 149A, Hawaii Revised Statutes) and the Hawaii Administrative Rules (Chapter 66, Title 4). There are approximately 1,110,000 acres in farmland, 7,500 farms, 6,400 agricultural workers, 3,800 Agricultural Operators, 1,200 certified applicators, 21 licensed Restricted Use Pesticide (RUP) dealers, 18 pesticide producing establishments, and four licensed aerial applicators in the state of Hawaii. Major crops in Hawaii include seed corn, coffee, papaya, bananas and nursery plants. Average farm size in Hawaii is 150 acres. HDA maintains a database of all pesticides licensed in Hawaii. The HDA Pesticide program consists of approximately 14 individuals over 4 islands performing inspection, education, registration, administrative, and other pesticide program activities.

The Hawaii Pesticide program is supported by both State (general and revolving) and federal (USDA and USEPA) funds. HDA and USEPA Region 9 had one active Performance Partnership Grant (PPG) with pesticide related activities to be carried out in Federal Fiscal Year 2012. The purpose of the PPG is to reduce paperwork and provide administrative relief and flexibility to HDA.

The FY12 end-of-year evaluation was primarily accomplished by reviewing quarterly reports and correspondence received from HDA throughout the year, and an on-site visit by Mary Grisier, project officer for HDA. Information gathered was compared to the outputs and standards in the cooperative agreements to determine if HDA had met its commitments.

II. FINANCIAL

A. Budget Analysis

The following table summarizes funding and expenditures for the FY12 cooperative agreement. In FY12, approximately three FTE were supported by EPA funding (Inspector, Pesticide Specialist, and Chemist).

At the time of this writing, final Financial Status Reports (FSRs) for FY12 were not due and had not been received.

Work Plan Component	EPA Funding	Grantee Funding*	Total Funding
Enforcement	$197,000	$35,055	$232,055
Programs	$ 81,125	$11,603	$ 92,728
C&T	$ 30,000	$30,255	$ 60,255
TOTAL	$308,125	$76,913	$385,038

* State is required to provide 50% match in C&T, 15% (by policy) for other programs.

Re-budgeting –There was no rebudgeting in FY12.

III. GENERAL GRANT ADMINISTRATION

A. Recommended Actions for Grants Office - None

IV. COMPLIANCE AND ENFORCEMENT

A. Grantee Reports

1. Pesticide Enforcement Outcome Measures

HDA reported on the three Office of Enforcement and Compliance Assurance (OECA) measures for pesticide enforcement (Appendix 1). Values reported were:

a. Repeat violator: 8% of actionable inspections included entities receiving an action in the past three years.
b. Verified compliance: 32% of actionable inspections resulted in verified compliance.
c. Cost per actionable inspection: $9,483.56 is the cost per actionable inspection.

Compared to FY11, there were slightly more repeat violators, but also a large increase in the percentage of inspections that resulted in verifiable compliance (up from 11% in FY11). In addition, the cost per actionable inspection decreased from $19,357 to $9,483.56.

2. Summary of 5700-33H reports – attached as Appendix 2.

3. Annual Summary of Inspections and Enforcement Actions

HDA exceeded the number of projected inspections (266 projected, 440 completed). The percentage of all reported inspections (440) that resulted in any enforcement action was 19%, up from 9% in FY11, with agricultural use inspections resulting in the highest percentage of actions of any inspection category (36%) followed by marketplace inspections (28%). Seventy warning letters were issued, and two cases were assessed fines in FY12, versus four in FY11. Eleven inspection files were referred to EPA for enforcement review and possible development in FY12, down from twenty-nine in FY11.

B. Case File and Enforcement Action Evaluation

1. Significant Cases (FIFRA Section 27)

There was one episode referred to HDA as a high level episode in FY12. However, upon further investigation, no link to pesticides was found, and the referral was cancelled. Each island maintains a separate list of all episodes and complaints received. These are recorded and reported to EPA.

2. Routine Inspections – other than Worker Protection

Forty five case files were reviewed. Inspection files were randomly selected from actionable and non-actionable inspections. Inspections selected represented the work of five different inspectors. Inspections continue to document compliance/non compliance with pesticide laws, and in most cases include necessary evidence such as photographs, labels and invoices. HDA forwards any inspections conducted with a federal credential, or that reveal a federal violation, to EPA. There were no Special Requests issued to HDA during FY12. HDA did not complete any container/containment inspections, as there are no facilities currently identified in Hawaii that meet the necessary criteria. The Pesticide Container/Containment Inspection and Enforcement Accomplishment Report (EPA C/C Form 5700-33H) is included in Appendix 2.

1. Oversight inspections (non-WPS) - none

C. Compliance Priority – Worker Protection Standard (WPS)

1. Reports

a) The Pesticide Worker Protection Standard Inspection and Enforcement Accomplishment Report (WPS Form 5700-33H) is included in Appendix 2.

2. Significant WPS Cases (FIFRA Section 27) - none

3. WPS oversight inspections – none

4. WPS case file evaluation

HDA conducted forty one WPS Tier 1 inspections at establishments throughout Hawaii, twenty of which were for-cause. Out of the total number, one civil complaint and three warnings were issued. Inspection files were complete and contained required information. Four Tier 2 inspections were also conducted. Inspections were of high quality and included appropriate documentation.

5. Worker Protection Risk-Based Targeting Strategy

a) Implementation of Risk-Based Targeting Strategy

A WPS targeting strategy was developed in 1994. Targeting was based partly on how many restricted-use pesticides were purchased by growers, as well as how many workers were employed by the establishment. Since that time, agriculture has changed dramatically in Hawaii. The number of large farms with many workers has greatly decreased. Farms are smaller (average farm size is 150 acres) and growers buy smaller quantities of pesticides. Inspectors have found that they can identify establishments that fall under the WPS by conducting typical agricultural use inspections and asking questions related to worker activity during the inspection. They will then return at a later date to conduct a WPS inspection. Larger establishments are inspected approximately every two years.

D. Inspection and Enforcement Support

1. Training

At the time of the EPA visit in November, 2012, HDA conducted an annual pesticide training workshop for all HDA Pesticide Program staff (inspectors, education, and registration staff) and outer Pacific Island pesticide programs. The workshop reflected on the previous year's accomplishments and established priorities and goals for the coming year. Highlights included completion of standard operating procedures for the Branch, completion of the draft QAPP, and involvement of staff in an investigation into illegal pesticide use on basil. Special focus was directed at reviewing the workplan commitments agreed upon between HDA and EPA. The Program Manager stressed the need for staff to focus on repeat violators, making sure that monthly checks are done to identify those locations that require a follow-up visit to ensure compliance. Medical monitoring and respirator fit-testing were provided to inspectors.

At the time of the review, HDA had seven federally-credentialed inspectors. Training records were properly maintained at the Honolulu office, and inspectors had met the commitments outlined in the FIFRA inspector credential authorization agreement. HDA intends to hire an additional inspector to assist with coverage for Oahu, where there is currently only one inspector.

TRAINING	DATE
C&T Exam Development	Oct. 2011
C&T Exam Development	May 2012
WRPM –Cody, WY	May 2012
Intermediate Registration Evaluation Course - VA	July 2012
ASPCRO – Seattle, WA	Aug. 2012
Enforcement PIRT - NC	Sept. 2012
C&T PREP – Davis, CA	Sept. 2012

2. Enforcement Response Policy

The Hawaii Department of Agriculture revised and adopted its Pesticide Enforcement Action and Penalty Assessment Schedule on October 24th, 2006. Review of case files indicates that HDA follows its enforcement response policy. There are several areas where the policy is in need of updating; the Department of Agriculture is currently working to fill positions on the Governor's Pesticide Advisory Committee, which when fully formed, will take up the issue of revision of pesticide regulations in Hawaii.

3. Neutral Inspection Scheme

Applicators that are likely to use more RUPs are inspected more frequently than those that do not. This is based on amounts of RUPs purchased divided by the number of applicators employed by a business. With regard to marketplace inspections, they are conducted primarily based on complaints, rather than through a neutral inspection scheme. This has been discussed during previous reviews as an area for additional focus by HDA. HDA should consider whether these overall approaches to targeting inspections are still appropriate and effective.

4. Inspection and Enforcement Procedures

Discussions were held throughout the year between HI inspection staff and EPA as procedural issues arose. HDA is encouraged to continue to identify those areas that are lacking in the ERP, so that at a future date, changes can be made. HDA has revised the Branch Standard Operating Procedures, which includes neutral inspection procedures. HDA has one case development officer that reviews all files as they come in from the inspection staff. There is a vacant Planner position in the Branch; the Program Manager hopes to fill this vacancy and cross-train the employee on case development.

5. Quality Assurance

HDA staff worked consistently on a revised QAPP during FY12. At the time of this writing, the draft QAPP and associated laboratory documentation, including over 30 standard operating procedures had been submitted and was under review in the Regional Office. During FY12, a second chemist was hired to assist in the Chemical Analysis Laboratory.

6. Special activities/investigations

In cooperation with EPA, HDA is providing ongoing support to outer Pacific island pesticide program staff on import, inspection, enforcement, and certification issues. As in previous years, HDA extended an invitation to outer island inspectors to attend the Inspector Workshop. Attendance at the workshop provides an opportunity for the inspectors to receive medical monitoring exams and respirator fit tests, as well as to participate in discussions with fellow inspectors.

In FY12, it was discovered that several growers of sweet basil had been using a restricted use pesticide (RUP) not labeled for use on basil. This investigation ultimately led to nine different farms suspected of using this RUP. HDA completed thorough inspections at these farms, and is now in the process developing enforcement actions. It is likely that four entities will receive monetary penalties and five will receive warning letters.

E. New Legislation and Regulations

There was no new pesticide-related legislation proposed or passed in FY12.

F. Action Items from Previous Reviews

Recommendation 09-02: HDA should revise and update quality assurance documents in FY10. EPA is available to assist with any questions that HDA or the Chemical Analysis Laboratory may have in these revisions.
Status: HDA worked on the revised QAPP during FY12, and in November provided a draft for EPA review. This recommendation is now closed.

Recommendation 10-01: A narrative end of year report, covering all program areas and due 40 days after the end of the fiscal year should be prepared and forwarded to the Regional Office as soon as possible.
Status: Narratives were included with each quarterly report for FY12. Timely reporting is appreciated. This recommendation is now closed.

Recommendation 10-02: HDA should review their enforcement penalty policy and identify areas that need revision or update.
Status: This was discussed during the end of year review, and it appears that once the Pesticide Advisory Committee takes this issue up, there will be movement in this area. HDA understands where the penalty policy has weaknesses and/or is problematic, and plans to strengthen this and other parts of HI's pesticide rules.

Recommendation 10-03: HDA should develop a neutral scheme for conducting marketplace inspections. One approach would be to select an EPA priority area (such as products that make public health claims) to create a neutral inspection scheme.
Status: This recommendation remains in effect; HDA should review its targeting strategies to ensure that they are still effective.

G. Conclusions and Recommendations for Compliance/Enforcement

HDA continues to maintain a quality enforcement program. HDA continued to re-inspect numerous establishments to assess compliance with the WPS in FY12. HDA is encouraged to revisit and revise its enforcement response policy, and maintain its focus on WPS enforcement. Policies and documents in need of revision and update should be identified and a plan put in place to make the necessary changes. HDA has made progress in addressing the issue of inspection backlog, but the case development officer would benefit from assistance with initial review of inspection files. HDA is planning to address this by hiring a planner in the coming year.

V. PROGRAMS

A. Worker Safety – C&T

1. Previous Recommendations - none

2. Accomplishments

a) Work-Plan Commitments & National Program Priorities

HDA had 1696 certified commercial and private applicators at the end of FY12; numbers that have remained unchanged from FY11. HDA updated the State Certification & Training plan, administered exams, and reviewed 154 courses for continuing education units, compared to 210 the previous year. HDA also provided eight presentations to certified applicators during the course of the year, down from twenty-nine the year before. In FY12, assignment changes took place within the education program with the end result being that there is now three staff in the education program at HDA, up from two in FY11. They cover exam administration and consultative visits on Oahu, Maui and Lanai. The island of Hawaii is covered by another employee based in Hilo. Twenty-three courses were monitored by HDA in FY12. Certification reporting in CPARD was completed by HDA in a timely manner.

HDA's databases for certified applicators as well as for tracking continuing education units are cumbersome and not integrated. The program manager for the Education section has ideas for updating and integrating this system, and has consulted with colleagues from other states who have done so. HDA is encouraged to identify the necessary steps towards improving these systems, and to discuss this with EPA during negotiations for FY14.

HDA worked closely with the Cooperative Extension Service (CES), meeting at least twice per year with representatives from CES Pesticide Applicator Training Program, at the University of Hawaii. HDA also meets with the Hawaii Pest Control Board, which reviews and approves applications for new pest control businesses in the state. University personnel travel to each of the neighbor islands to prepare applicators for the certification exam on a yearly basis.

Certification cards issued in Hawaii currently have a photo ID and bar code. Annual C&T Plan Reports for Hawaii and other states are available at: http://cpard.wsu.edu/

3. PART Review Measures - none

4. State/Tribe Feedback - none

5. Conclusions and Recommendations

All negotiated outputs have been satisfactorily met for FY12. HDA should explore ways to integrate tracking systems for education and licensing. Ideas for a possible supplemental project for FY14 should be shared with EPA during upcoming negotiations.

B. Worker Safety - WPS

1. Previous Recommendations - none

2. Accomplishments

a) Work-Plan Commitments & National Program Priorities

HDA conducted 67 consultative visits, including 18 WPS-related visits that reached 144 people. Consultative visits are scheduled when a new applicator becomes certified, or, if an applicator has received a notice of warning. A visit may be made to ensure that the applicator has subsequently come into compliance. HDA is also responding to a recent increase in Chinese and Laotian immigrant farmers on Oahu by providing pesticide safety and WPS training at key locations. HDA also provided outreach using the updated How to Comply Manual to agricultural establishments. HDA meets several times per year with the University of Hawaii Cooperative Extension and the Pest Control Board of the Department of Commerce and Consumer Affairs to discuss training and WPS issues.

3. PART Review Measures - none

4. State/Tribe Feedback - none

5. Conclusions and Recommendations

All negotiated outputs have been satisfactorily met for FY12.

C. Water Quality

1. Previous Recommendations - none

2. Accomplishments

a) Work-Plan Commitments & National Program Priorities:

HDA continues to review new pesticide products for groundwater and surface water concerns. At the time of this writing, HDA had not yet updated the Pesticides of Interest Tracking System (POINTS) for FY12, so numbers remain the same from FY11. Specifically, HDA has evaluated 47 of 71 Pesticides of Interest (66%), is actively managing 15 of 16 Pesticides of Concern (POC; 94%) and is demonstrating progress for 9 of 15 actively managed POCs (60%). Hawaii continues to use modeling to determine whether new chemicals may have the potential to leach into groundwater. HDA continually reviews pesticide labels to ensure that they include necessary language for protection of ground and surface water. HDA has identified several labels, including rodenticides and termiticides that do not have appropriate water quality protection language. Restricted use pesticide sales records are monitored to identify products that may affect water quality. HDA has discussions with HI Department of Health (DOH) as well as registrants to discuss pesticides of concern for surface and ground water. The HI Department of Health is responsible for implementing the pesticides NPDES permit program in Hawaii, and is currently working to revise Hawaii Administrative Rules to include these provisions.

3. PART Review Measures - none

4. State/Tribal Concerns - none

5. Conclusions and Recommendations

All negotiated outputs have been satisfactorily met for FY12.

D. Endangered Species

1. Previous Recommendations - none

2. Accomplishments

a) Work-Plan Commitments & National Program Priorities

HDA continues to consult and coordinate with other State agencies on Section 18 emergency exemption requests and special local needs registration applications. HDA assigned a staff person to work on endangered species activities during FY12.

3. PART Review Measures - none

4. State/Tribe Feedback – none

5. Conclusions and Recommendations

All negotiated outputs have been satisfactorily met for FY12.

APPENDIX 1

Pesticide Enforcement Outcome Measure Reporting Form

Grantee Hawaii Department of Agriculture, Pesticides Branch

Fiscal Year 2012

Measure No. 1 - Repeat Violator

A. Total # of Regulated Entities Receiving Enforcement Actions	B. Total # of Entities Receiving Subsequent Enforcement Actions (i.e. subset of column A)	C. Repeat Violator Measure—B/A
75	6	0.08

Measure No. 2 - Complying Actions

D. **Total # of Enforcement Actions Resulting in Verified Compliance:** 24

E. **Total # of Enforcement Actions (from form 5700-33H):** 75

F. **Complying Actions Measure—D/F:** 0.32

Measure No. 3 - Efficiency

G. **Grantee Pesticide Enforcement Funding: $** 488,142.00

H. **EPA Pesticide Enforcement Funding: $** 223,125.00

Base Enforcement 167,000.00

Worker Protection 26,125.00

Enforcement Discretionary 30,000.00

Lab Equipment 0.00

I. **Efficiency Measure—(G+H)/E:** 9,483.56

(Revised 10/2005)

App2

FIFRA/TSCA TRACKING SYSTEM
ENFORCEMENT ACTIONS RESULTING FROM INSPECTIONS
REPORTING METHOD: STATE + COOPERATIVE ACTIVITY
TOTALS FOR Hawaii (HI)

PROGRAM: GRANT1

FOR THE PERIOD - FROM: 10/01/2011
TO: 09/30/2012

REPORT DATE: 10/30/12
LAST UPDATE: 10/30/12

ENFORCEMENT ACCOMPLISHMENTS	AGRICULTURE USE	AGRICULTURE FOLLOW UP	NON-AGRICULTR USE	NON-AGRICULTR FOLLOW UP	EXP USE INSPEC	PRODUC ESTABL	MARKET PLACE	IMPORT	EXPORT	CERTIF APPLCR RECORD	RESTRC USE PE ST DLR	TOTAL
INSPECTIONS	122	49	87	42	1	3	32	5	0	88	11	440
FEDERAL FACILITIES	0	0	1	0	0	0	0	0	0	0	0	1
WORKER PROTECTION	0	0	0	0	0	0	0	0	0	0	0	0
GROUND WATER	0	0	0	0	0	0	0	0	0	0	0	0
ENDANGERED SPECIES	0	0	0	0	0	0	0	0	0	0	0	0
CANCELLATIONS/SUSPENSIONS	0	0	0	0	0	0	0	0	0	0	0	0
SAMPLES PHYSICAL	0	74	0	28	0	0	0	0	0	0	0	102
DOCUMENTARY	0	0	0	0	0	0	32	0	0	0	0	32
CIVIL ACTIONS	2	0	0	0	0	0	3	0	0	0	0	5
CRIMINAL ACTIONS	0	0	0	0	0	0	0	0	0	0	0	0
ADMINISTRATIVE HEARINGS	0	0	0	0	0	0	0	0	0	0	0	0
LIC./CERT. SUSPENSIONS	0	0	0	0	0	0	0	0	0	0	0	0
LIC./CERT. REVOCATIONS	0	0	0	0	0	0	0	0	0	0	0	0
LIC./CERT. COND OR MOD	0	0	0	0	0	0	0	0	0	0	0	0
WARNING LETTERS	42	6	10	11	0	0	1	0	0	0	0	70
STOP SALE, SEIZURE, ETC.	0	0	0	0	0	0	0	0	0	0	0	0
CASES FORWARDED TO EPA	0	0	3	0	0	3	5	0	0	0	0	11
OTHER ENFORCEMENT ACTIONS	0	0	0	0	0	0	0	0	0	0	0	0
TOTAL NUMBER OF ACTIONABLE INSPECTIONS-	44	6	13	11	0	3	9	0	0	0	0	86
PERCENT OF INSPECTIONS- RESULTING IN ACTIONS--	36.1	12.2	14.9	26.2	0.0	100.0	28.1	0.0	0.0	0.0	0.0	19.5
PERCENT OF TOTAL ACTIONS---	51.2	7.0	15.1	12.8	0.0	3.5	10.5	0.0	0.0	0.0	0.0	100.0
NUMBER OF CASES ASSESSED FINES	1	0	0	0	0	0	1	0	0	0	0	2

** NO DATA FOUND FOR QUARTER 1 **

** NO DATA FOUND FOR QUARTER 3 **

APP 2 p2

United States
Environmental Protection Agency
Washington, DC 20460

Pesticide Worker Protection Standard Inspection and Enforcement Accomplishment Report

State: Hawaii | Fiscal Year: 2012 | Reporting Period: 10/01/11-09/30/12 | ☑ Total Program Accomplishment

Enforcement Accomplishments This Reporting Year	WPS Tier I Inspection		WPS Tier II Inspection		Total Inspections	*Inspections at Facilities Claiming Family Exemption
	Use	For Cause	Use	For Cause		
Total Inspections Conducted	21	20	4	0	45	0
WPS Enforcement Actions						
Civil Complaints Issued	1	0	0	0	1	
Criminal Complaints Referred	0	0	0	0	0	
Administrative Hearings Conducted	0	0	0	0	0	
Licence/Certification Suspension	0	0	0	0	0	
Number of Warnings Issued	3	0	0	0	3	
Stop-Sale, Use and Removal Order (SSURO)	0	0	0	0	0	
Cases Forwarded to EPA for Action	0	0	0	0	0	
Other Enforcement Actions (e.g. Advisory Letters)	0	0	0	0	0	
Number of Cases Assessed Fines					0	

Violations during WPS Inspections

WPS Violation Categories	Number of Violations
1. Pesticide Safety Training	4
2. Central Posting	3
3. Notice of Application	3
4. Entry Restrictions	0
5. Personal Protective Equipment	0
6. Mix/Loading, Application Equip & Applications	0
7. Decontamination	2
8. Emergency Assistance	0
9. Information Exchange	0
10. Retaliation	0

EPA WPS Form 5700-33H

* This Column is a subset of the WPS Tier I and WPS Tier II Columns combined to collect data on inspections conducted at facilities claiming the Immediate Family Exemption.

APP 2 p3

United States
ENVIRONMENTAL PROTECTION AGENCY
Washington, DC 20460

Pesticide Container/Containment Inspection and Enforcement Accomplishment Report

State/Tribe: Hawaii | Fiscal Year: Sep 30 2012 | Reporting Period: Forth Quarter | ☐ Total Program Accomplishments | ☐ Workplan Activities Only

Enforcement Accomplishments This Reporting Year	PEI with Containment	Non-PEI Containment	Total
Total Inspections Conducted	0	0	0
Samples Collected — Physical	0	0	0
Documentary	0	0	0
Civil Complaints Issued	0	0	0
Criminal Complaints Referred	0	0	0
Administrative Hearings Conducted	0	0	0
Number of Warnings Issued	0	0	0
Stop-Sale, Use and Removal Order (SSURO)	0	0	0
Cases Forwarded to EPA for Action	0	0	0
Other Enforcement Actions (e.g. Advisory Letters)	0	0	0
Number of Cases Assessed Fines	0	0	0

Container/Containment Violations	
Refillable Containers	
1. Deficient labeling (i.e. cleaning and disposal instructions)	0
2. Deficient container design (valves, openings)	0
3. Producing establishment registration violations	0
4. No contract manufacturing agreement, residue removal instructions, list of acceptable containers	0
5. Deficient management procedures & operation	0
6. Record keeping	0
Containment	
7. Secondary containment & pads – capacity/design	0
8. Secondary containment & pads – site management	0
9. Secondary containment & pads – record keeping	0
Total Violations	0

Reset Form

EPA Container/Containment Form 5700-33H (01/10)

ED_001297_00049288

U.S. Environmental Protection Agency

Hawaii Department of Agriculture

FY2013 Draft End-of-Year Review

Pesticide Performance Partnership Grant

EXHIBIT 11

Executive Summary- This report covers workplan activities conducted in FY13, and is based on discussions and review of documents throughout the year and during the end of year visit. Discussions were held during the end of year visit that focused on recent changes to the pesticide program at Hawaii Department of Agriculture (HDOA). Recommendations for improvements can be found within the body of this report. Recommendations focus primarily on addressing a backlog of inspection files that need review, revising policies, especially the enforcement response policy, and increasing the number of WPS Tier 1 inspections to more closely match previous years' numbers. It should be noted that HDOA had already started to make progress on our recommendations at the time of this writing. This report covers the second year of a three-year performance partnership grant between Hawaii Department of Agriculture and EPA Region 9. This grant was put into place to ease administrative burdens on HDOA and to allow for more long-term planning for the Pesticide program.

I. BACKGROUND

A. General

1. Project Period: October 1, 2012 – September 30, 2013.

2. EPA Assistance Agreement Number: #BGOOT64412 **3. Review method:** On-site

4. Review participants:

EPA: Mary Grisier, Hawaii Pesticide Project Officer Grantee: Thomas Matsuda, Pesticide Program Manager, Avis Onaga, Case Preparation Officer, and Dean Yoshizu, Compliance Officer

5. Review date(s) and location: April 28, 2014-May 1, 2014 at the Hawaii Department of Agriculture offices in Honolulu.

B. Scope of Review

The Hawaii Department of Agriculture (HDOA) has primary enforcement responsibility over pesticide use activities in the State of Hawaii and is the lead state agency for the enforcement of the Hawaii Pesticides Law (Chapter 149A, Hawaii Revised Statutes) and the Hawaii Administrative Rules (Chapter 66, Title 4). There are approximately 1,110,000 acres in farmland, 7,500 farms, 6,400 agricultural workers, 3,800 Agricultural Operators, 1,200 certified applicators, 22 licensed Restricted Use Pesticide (RUP) dealers, 18 pesticide producing establishments, and seven licensed aerial applicators in the state of Hawaii. Major crops in Hawaii include seed corn, coffee, papaya, macadamia and nursery plants. Average farm size in Hawaii is 150 acres. HDOA maintains a database of all pesticides licensed in Hawaii. The HDOA Pesticide program consists of approximately 14 individuals over 4 islands performing inspection, education, registration, administrative, and other pesticide program activities.

The Hawaii Pesticide program is supported by both State (general and revolving) and federal (USDA and USEPA) funds. HDOA and USEPA Region 9 had one active Performance Partnership Grant (PPG) with pesticide related activities to be carried out in Federal Fiscal Year 2013. The purpose of the PPG is to reduce paperwork and provide administrative relief and flexibility to HDOA.

The FY13 end-of-year evaluation was primarily accomplished by reviewing quarterly reports and correspondence received from HDOA throughout the year, and an on-site visit by Mary Grisier, project officer for HDOA. Information gathered was compared to the outputs and standards in the cooperative agreements to determine if HDOA had met its commitments.

II. FINANCIAL

A. Budget Analysis

The following table summarizes funding and expenditures for the FY13 cooperative agreement. In FY13, approximately three FTE were supported by EPA funding (Inspector, Pesticide Specialist, and Chemist).

Interim Financial Status Reports (FSRs) for FY13 were received and indicated that HI Department of Agriculture was drawing down funds in an appropriate manner, and did not have an excess amount of remaining funds at the end of FY13. It should be noted that the project period extends to September 30, 2014, so HDOA may spend remaining funds up until that date.

Work Plan Component	EPA Funding	Grantee Funding*	Total Funding
Enforcement	$212,621	$42,617	$255,238
Programs	$139,704	$26,394	$166,158
C&T	$ 30,000	$34,948	$ 64,948
TOTAL	$382,325	$103,959	$486,284

* State is required to provide 50% match in C&T, 15% (by policy) for other programs.

Re-budgeting –There was no re-budgeting in FY13.

III. GENERAL GRANT ADMINISTRATION

A. *Recommended Actions for Grants Office* - None

IV. COMPLIANCE AND ENFORCEMENT

A. Grantee Reports

1. Pesticide Enforcement Outcome Measures

HDOA reported on the three Office of Enforcement and Compliance Assurance (OECA) measures for pesticide enforcement (Appendix 1). Values reported were:

a. Repeat violator: 0% of actionable inspections included entities receiving an action in the past three years.
b. Verified compliance: 74% of actionable inspections resulted in verified compliance.
c. Cost per actionable inspection: $20,279.91 is the cost per actionable inspection.

The cost per actionable inspection increased significantly from $9,483.56 in FY12 to $20,279.91. It should be noted that HDOA has a large backlog of inspection files that have not been processed; the values for the above measures are therefore not reflective of the actual costs.

2. Summary of 5700-33H reports – attached as Appendix 2.

3. Annual Summary of Inspections and Enforcement Actions

HDOA exceeded the number of projected inspections (266 projected, 430 completed). This is approximately 10 fewer inspections conducted than in FY12. Twenty warning letters were issued, down from 70 in the previous year, and three cases were assessed fines in FY13, versus two in FY12. There were no inspection files referred to EPA for enforcement review and possible development in FY13, while there were eleven forwarded in FY12. This is due in large part to an extensive backlog of inspection files to be reviewed and processed by HDOA.

B. Case File and Enforcement Action Evaluation

1. Significant Cases (FIFRA Section 27)

There were no high level episodes referred to HDOA in FY13. Each island maintains a separate list of all episodes and complaints received. These are recorded and reported to EPA.

2. Routine Inspections – other than Worker Protection

Forty inspection files were reviewed. Inspection files were randomly selected from actionable and non-actionable inspections. Inspections selected represented the work of five different inspectors. Inspections continue to document compliance/non compliance with pesticide laws, and in most cases include necessary evidence such as photographs, labels and invoices. It should be noted that by the time the project officer reviews inspection files, they have been reviewed and errors have been corrected by the HI case developer or the inspector. Discussions with the case developer indicate that inspectors, in general, need to pay closer attention to ensuring that reports are clearly written, grammatical errors are corrected, and that reports are "enforcement ready". While no inspection files were forwarded in FY13, it is a requirement that states forward any inspections conducted with a federal credential, or that reveal a federal violation, to EPA. **Recommendation 13-01**: HDOA must forward inspections to EPA that either 1) were conducted with a Federal credential, or 2) reveal a potential federal violation.

There were no Special Requests issued to HDOA during FY13. HDOA did not complete any container/containment inspections, as there are no facilities currently identified in Hawaii that meet the necessary criteria. The Pesticide Container/Containment Inspection and Enforcement Accomplishment Report (EPA C/C Form 5700-33H) is included in Appendix 3.

1. Oversight inspections (non-WPS) - none

C. Compliance Priority – Worker Protection Standard (WPS)

1. Reports

a) The Pesticide Worker Protection Standard Inspection and Enforcement Accomplishment Report (WPS Form 5700-33H) is included in Appendix 4.

2. Significant WPS Cases (FIFRA Section 27) - none 3. WPS oversight inspections – none 4. WPS case file evaluation

HDOA conducted thirteen neutral-scheme WPS Tier 1 inspections at establishments throughout Hawaii, down from forty in FY12. There were no enforcement actions issued for any Tier 1 inspections conducted in FY13. One Tier 2 inspection was also conducted, down from four the previous year.

Recommendation 13-02: HDOA has seen a downward trend in overall inspection activity in FY13, especially with regard to WPS Tier 1 inspections. HDOA should make every effort to increase the number of WPS Tier 1 inspections in the coming year, in keeping with past practices.

5. Worker Protection Risk-Based Targeting Strategy

a) Implementation of Risk-Based Targeting Strategy

A WPS targeting strategy was developed in 1994. Targeting was based partly on how many restricted-use pesticides were purchased by growers, as well as how many workers were employed by the establishment. Since that time, agriculture has changed dramatically in Hawaii. The number of large farms with many workers has greatly decreased. Farms are smaller (average farm size is 150 acres) and growers buy smaller quantities of pesticides. Inspectors have found that they can identify establishments that fall under the WPS by conducting routine agricultural use inspections and asking questions related to worker activity during the inspection. They will then return at a later date to conduct a WPS inspection. Larger establishments are inspected approximately every two years.

D. Inspection and Enforcement Support

1. Training

HDOA conducts an annual pesticide training workshop for all HDOA Pesticide Program staff (inspectors, education, and registration staff) and outer Pacific Island pesticide programs in November of each year. The workshop also included medical monitoring and respirator fit-testing for inspectors. The project officer attends this workshop, in conjunction with the end of year visit. Due to furloughs, the project officer was unable to travel in November, and did not conduct the end of year review until April, 2014. The workshop, while a valuable source for inspectors to get updates on programs and to network with colleagues, will have a format change for the coming year. There will be more focus on training, including report writing and inspection techniques, as well as field exercises. The workshop will be extended to a full five days. An informal request has been made to EPA to send the enforcement liaison to the workshop to ensure that EPA requirements are fully woven in the workshop.

Recommendation 13-03: HDOA should formally request that EPA send the enforcement liaison to the upcoming November workshop at the HI Department of Agriculture. This will ensure that state inspectors are provided the most up-to-date requirements for their work under the cooperative agreement.

In FY13, HDOA had seven federally-credentialed inspectors. Training records were properly maintained at the Honolulu office, and inspectors had met the commitments outlined in the FIFRA inspector credential authorization agreement. HDOA hired an additional inspector for Oahu during FY13, and her training began immediately by accompanying the senior inspector on Oahu on all types of pesticide inspections. The credential was issued in August, 2014.

Below is a list of training courses attended by HDOA staff in FY13:

TRAINING/MEETING	DATE
ALSTAR/NPIRS Training	10/2012

PREP-Compliance Monitoring	4/2013
PREP – Program Management for New Supervisors	7/2013
North American Chemical Residue Workshop	7/2013
National Pesticide Applicator C&T Workshop	8/2013
PREP – Sr. Executive Lab Mgt.	10/2013

2. Enforcement Response Policy

The Hawaii Department of Agriculture revised and adopted its Pesticide Enforcement Action and Penalty Assessment Schedule on October 24th, 2006. Review of case files indicates that HDOA follows its enforcement response policy, however there are numerous areas where the policy is in need of updating. The Department of Agriculture has nearly completed the task of filling positions on the Governor's Pesticide Advisory Committee, which when fully formed, will take up the issue of revision of pesticide regulations in Hawaii. HDOA is encouraged to continue to identify those areas that are lacking in the ERP, so that at a future date, changes can be made.

3. Neutral Inspection Scheme

Applicators that are likely to use more RUPs are inspected more frequently than those that do not. This is based on amounts of RUPs purchased divided by the number of applicators employed by a business. With regard to marketplace inspections, they are conducted primarily based on complaints, rather than through a neutral inspection scheme. This has been discussed during previous reviews as an area for additional focus by HDOA. HDOA should consider whether these overall approaches to targeting inspections are still appropriate and effective.

4. Inspection and Enforcement Procedures

Discussions were held throughout the year between HI inspection staff and EPA as procedural issues arose. HDOA has revised the Branch Standard Operating Procedures, which includes neutral inspection procedures. HDOA has one case development officer that reviews all files as they come in from the inspection staff. Over the past several years, a backlog of inspection files has been building. The case developer, in addition to working up inspection reports, also responds to numerous information requests from the public. This has begun to take up a large percentage of her time, leaving little time to review and develop cases. The more serious cases that lead to civil complaints are sent to the deputy attorney general's office for review and concurrence. The deputy AG's office also has a backlog of civil cases to review, which results in penalty actions not being issued. Currently, there are at least ten civil complaints in the deputy AG's office awaiting review, dating back to 2012. The Pesticide Program has at least 15 additional complaints waiting to be submitted. These enforcement-related issues and how to resolve them were the primary focus of the FY13 review. HDOA must take immediate action to reduce the backlog of inspection reports, and to identify long-term solutions to this issue as well as to work with the Deputy Attorney General's office to reduce the backlog of civil actions that have not been issued by that office.

5. Quality Assurance

HDOA staff worked consistently on a revised Quality Assurance Program Plan (QAPP) during FY13, and the QAPP was approved by EPA on February 24, 2014. The Chemical Analysis Laboratory operates a state-of-the-art pesticide residue laboratory for the analysis of a wide range of plant, soil, product and environmental samples in support of enforcement and registration activities. In 2013, the Hawaii Department of Agriculture Laboratory (Lab) participated in the Pesticide Residue Check Sample Program administered by the State of Wisconsin Department of Agriculture. The Lab received soil samples in February 2013 and plant samples in October 2013. The Lab performed well, correctly identifying all pesticides in each of the samples and not reporting any false positive results. They also accurately determined concentrations for 7 of 8 pesticides in soil and 7 of 8 pesticides in plant material. For cyfluthrin and propiconazole, the two pesticides with results outside of acceptable limits, the Lab is working to refine methods.

6. Special Activities

In cooperation with EPA, HDOA is providing ongoing support to outer Pacific island pesticide program staff on import, inspection, enforcement, and certification issues. As in previous years, HDOA extended an invitation to outer island inspectors to attend the Inspector Workshop. Attendance at the workshop provides an opportunity for the inspectors to receive medical monitoring exams and respirator fit tests, as well as to participate in discussions with fellow inspectors and to receive important training.

E. New Legislation and Regulations

Two pesticide-related pieces of State legislation were proposed in FY13.

Act 105 – Rewrites Section 2, Chapter 49A of the HI Revised Statutes	Implements a pesticide use reporting system for restricted use pesticides, to be posted on the HDOA website.(**Proposed**)
HR 100 and HR 129	Requests HI Dept. of Health to establish a taskforce to study the health effects of Atrazine, and report to the legislature by 10/31/13.(**Passed**)

Local Legislation - The County Council of Kauai passed a law requiring large users of restricted use pesticides to disclose what they are using and in what quantities. As of this writing, a Federal judge had struck down this law, citing preemption by the State. The County Council of Hawaii passed a bill restricting open air propagation of genetically modified organisms on Hawaii, continuing a trend by county leaders to seek local control over crops grown and pesticides used.

F. Action Items from Previous Reviews

Recommendation 10-02: HDOA should review their enforcement penalty policy and identify areas that need revision or update.
Status: This was discussed during the end of year review, and during the FY15 cooperative agreement negotiations. HDOA understands where the penalty policy has weaknesses and/or is problematic, and plans to strengthen this and other parts of HI's pesticide rules in the near future. These changes will require a formal change in Hawaii's Pesticide Law.

Recommendation 10-03: HDOA should develop a neutral scheme for conducting marketplace inspections. One approach would be to select an EPA priority area (such as products that make public health claims) to create a neutral inspection scheme. **Status**: This recommendation remains in effect; HDOA should review its targeting strategies to ensure that they are still effective.

G. Conclusions and Recommendations for Compliance/Enforcement

EPA has significant concerns with the backlog of inspection files to be processed, and the resulting lack of enforcement actions issued, as well as the lack of inspections forwarded to EPA for review/enforcement.
Recommendation 13-04: HDOA must identify ways to address the backlog of inspection files, whether through assigning inspection staff to review files or hiring additional case developers. Solutions to the backlog that also exists with cases at the Deputy Attorney General's office must also be identified. (NOTE: At the time of this writing, HDOA had assigned inspection staff to assist in reviewing inspection files, in order to decrease the backlog.)
Recommendation 13-05: HDOA is asked to identify those policies and documents in need of revision and a plan put in place to make the necessary updates. (NOTE: At the time of this writing, several changes had been put in place, including additional personnel to review inspection files, and the AG's office had also hired an assistance to focus on pesticide civil cases.)

V. PROGRAMS

A. Worker Safety – C&T

1. Previous Recommendations - none 2. Accomplishments

a) Work-Plan Commitments & National Program Priorities

HDOA had 1106 certified commercial and 375 private applicators at the end of FY13, a total that has decreased by nearly 500 from FY12. HDOA administered exams and reviewed 199 courses for continuing education units, compared to 154 the previous year. HDOA also provided 37 presentations to certified applicators during the course of the year, up from eight the year before. Honolulu staff cover exam administration and consultative visits on Oahu, Kauai, Maui and Molokai. The island of Hawaii is covered by an additional employee based in Hilo. Fifteen courses were monitored by HDOA in FY13, down from 23 in FY12. Certification reporting in CPARD was completed by HDOA in a timely manner.

HDOA's databases for certified applicators as well as for tracking continuing education units are cumbersome and not integrated. The Pesticide Branch is embarking on a project to integrate the Education, Enforcement and Registration programs into one cohesive Integrated Pesticides Information System. This is welcome news, and will ultimately be an important tool for staff once it is operational.

HDOA worked closely with the Cooperative Extension Service (CES), meeting at least twice per year with representatives from CES Pesticide Applicator Training Program, at the University of Hawaii. HDOA also meets with the Hawaii Pest Control Board, which reviews and approves applications for new pest control businesses in the state. University personnel travel to each of the neighbor islands to prepare applicators in core topics for the certification exam on a yearly basis. The University of HI is currently revising the core exam to make the questions more applicable and connected to the study material that applicators use to prepare for the exam.

Certification cards issued in Hawaii currently have a photo ID and bar code. Annual C&T Plan Reports for Hawaii and other states are available at: http://cpard.wsu.edu/

3. PART Review Measures - none 4. State/Tribe Feedback - none 5. Conclusions and Recommendations

All negotiated outputs have been satisfactorily met for FY13.

B. Worker Safety - WPS

1. Previous Recommendations - none 2. Accomplishments

a) Work-Plan Commitments & National Program Priorities

HDOA conducted 33 consultative visits focused on WPS compliance. Consultative visits are scheduled when a new applicator becomes certified, or, if an applicator has received a notice of warning. A visit may be made to ensure that the applicator has subsequently come into compliance. HDOA is also responding to a recent increase in Chinese and Laotian immigrant farmers on Oahu by providing pesticide safety and WPS training at key locations. HDOA also provided outreach using the updated How to Comply Manual to agricultural establishments. HDOA meets several times per year with the University of Hawaii Cooperative Extension and the Pest Control Board of the Department of Commerce and Consumer Affairs to discuss training and WPS issues. In FY13, HDOA began holding Farmer Resource Workshops, designed as a "one stop shop" for farmers to obtain information on a wide range of topics. Topics range from proper pesticide use, agriculture loans and insurance, to soil conservation and air pollution regulations. These workshops have been held on Oahu, Maui and Kauai, and have been well-received.

In FY13, HDOA received special one-time funding to develop a slideshow which will be translated into several languages (Ilocano, Laotian, Mandarin, Cantonese and Tagalog) to provide workers and handlers with pesticide safety information. At the time of this writing, the slideshow was in the editing phase, and near completion in all languages. HDOA hopes to complete the project by September 30, 2014.

3. PART Review Measures - none

4. State/Tribe Feedback - none

5. Conclusions and Recommendations

All negotiated outputs have been satisfactorily met for FY13.

C. *Water Quality*

1. Previous Recommendations - none

2. Accomplishments

a) Work-Plan Commitments & National Program Priorities:

HDOA continues to review new pesticide products for groundwater and surface water concerns. At the end of FY13, the Pesticides of Interest Tracking System (POINTS) had not been updated. Values remained the same as in FY 12; specifically, HDOA has evaluated 47 of 71 Pesticides of Interest (66%), is actively managing 15 of 16 Pesticides of Concern (POC; 94%) and is demonstrating progress for 9 of 15 actively managed POCs (60%). HDOA should update the POINTS system to reflect any changes, especially to indicate any additional pesticides currently under evaluation. Hawaii continues to use modeling to determine whether new chemicals may have the potential to leach into groundwater. Restricted use pesticide sales records are monitored to identify products that may affect water quality. HDOA has discussions with HI Department of Health (DOH) as well as registrants to discuss pesticides of concern for surface and ground water. The HI Department of Health is responsible for implementing the pesticides NPDES permit program in Hawaii.

3. PART Review Measures - none 4. State/Tribal Concerns - none 5. Conclusions and Recommendations

<u>**Recommendation 13-06:**</u> HDOA should ensure that the POINTS system is updated on a yearly basis, and that progress is made in evaluating pesticides of interest to Hawaii. The POINTS database has been updated, and all negotiated outputs due in FY13 have now been completed.

D. Endangered Species

1. Previous Recommendations - none 2. Accomplishments

a) Work-Plan Commitments & National Program Priorities

HDOA continues to consult and coordinate with other State agencies on Section 18 emergency exemption requests and special local needs registration applications.

3. PART Review Measures - none 4. State/Tribe Feedback – none 5. Conclusions and Recommendations

All negotiated outputs have been satisfactorily met for FY13.

U.S. Environmental Protection Agency

Hawaii Department of Agriculture

FY2014 Final End-of-Year Review

Pesticide Performance Partnership Grant

EXHIBIT 12

Executive Summary- This report covers workplan activities conducted in FY14, and is based on discussions and review of documents throughout the year and during the end of year visit. Discussions were held during the end of year visit that focused on recent changes to the pesticide program at Hawaii Department of Agriculture (HDOA). Recommendations for improvements can be found within the body of this report. Recommendations focus primarily on reducing a backlog of inspection files (several hundred) that need review. HDOA should also focus on revising the enforcement response policy, and increasing the number of WPS Tier 1 inspections to more closely match numbers in previous years. Highlights include a successful pilot school IPM program initiated at a local elementary school. The pilot is likely to lead to broader implementation of IPM in schools throughout Hawaii. This report covers the final year of a three-year performance partnership grant between Hawaii Department of Agriculture and EPA Region 9. This grant was put into place to ease administrative burdens on HDOA and to allow for more long-term planning for the Pesticide program. Thomas Matsuda completed his second and final year as the regional representative to the State FIFRA Issues Research and Evaluation Group (SFIREG).

I. BACKGROUND

A. General

1. **Project Period:** October 1, 2013 – September 30, 2014.

2. **EPA Assistance Agreement Number:** #BGOOT64412-2

3. **Review method:** On-site

4. **Review participants:**

EPA: Mary Grisier, Hawaii Pesticide Project Officer Grantee: Thomas Matsuda, Pesticide Program Manager, Avis Onaga, Case Preparation Officer, and Dean Yoshizu, Compliance Officer

5. **Review date(s) and location:** November 17-20, 2014 at the Hawaii Department of Agriculture offices in Honolulu.

B. Scope of Review

The Hawaii Department of Agriculture (HDOA) has primary enforcement responsibility over pesticide use activities in the State of Hawaii and is the lead state agency for the enforcement of the Hawaii Pesticides Law (Chapter 149A, Hawaii Revised Statutes) and the Hawaii Administrative Rules (Chapter 66, Title 4). There are approximately 1,110,000 acres in farmland, 7,500 farms, 6,400 agricultural workers, 3,800 Agricultural Operators, 1,200 certified applicators, 22 licensed Restricted Use Pesticide (RUP) dealers, 18 pesticide producing establishments, and seven licensed aerial applicators in the state of Hawaii. Major crops in Hawaii include seed corn, coffee, papaya, macadamia and nursery plants. Average farm size in Hawaii is 150 acres. HDOA maintains a database of all pesticides licensed in Hawaii. The HDOA Pesticide program consists of approximately 14 individuals over 4 islands performing inspection, education, registration, administrative, and other pesticide program activities.

The Hawaii Pesticide program is supported by both State (general and revolving) and federal (USDA and USEPA) funds. HDOA and USEPA Region 9 had one active Performance Partnership Grant (PPG) with pesticide related activities to be carried out in Federal Fiscal Year 2014. The purpose of the PPG is to reduce paperwork and provide administrative relief and flexibility to HDOA. FY14 was the third year of a three-year agreement.

The FY14 end-of-year evaluation was primarily accomplished by reviewing quarterly reports and correspondence received from HDOA throughout the year, and an on-site visit by Mary Grisier, project officer for HDOA. Information gathered was compared to the outputs and standards in the cooperative agreements to determine if HDOA had met its commitments.

II. FINANCIAL

A. Budget Analysis

The following table summarizes funding and expenditures for the FY14 cooperative agreement. In FY14, approximately three FTE were supported by EPA funding (Inspector, Pesticide Specialist, and Chemist).

Final Financial Status Reports (FSRs) for FY14 were received and indicated that HI Department of Agriculture drew down funds in an appropriate manner.

Work Plan Component	EPA Funding	Grantee Funding*	Total Funding
Enforcement	$186,200	$35,745	$221,945
Programs	$116,125	$20,930	$137,055
C&T	$ 30,000	$30,063	$ 60,063
Supplemental $	$ 94,600	$ 9,945	$104,545
TOTAL	$426,925	$ 96,693	$523,618

* State is required to provide 50% match in C&T, 15% (by policy) for other programs.

Re-budgeting –There was no re-budgeting in FY14.

III. GENERAL GRANT ADMINISTRATION

A. Recommended Actions for Grants Office - None

IV. COMPLIANCE AND ENFORCEMENT

A. Grantee Reports

1. Summary of <u>5700-33H</u> reports – attached as Appendix 1.

2. Annual Summary of Inspections and Enforcement Actions

HDOA exceeded the number of projected inspections (307 projected, 388 completed). This is approximately 42 fewer inspections conducted than in FY13. It should be noted that a senior inspector on the island of Hawaii retired in December, 2013. This is a factor in the inspection shortfall for FY14. HDOA issued one civil complaint in FY14. Forty two warning letters were issued, up from 20 in the previous year, and one case was assessed a fine in FY14, versus three in FY13. There were eight inspection files referred to EPA for enforcement review and possible development in FY14, while there were none forwarded in FY13.

B. Case File and Enforcement Action Evaluation

1. Significant Cases (FIFRA Section 27)

There were three high level episodes referred to HDOA in FY14. For all three of the incidents, violations were found and warning letters were issued. EPA was given proper notification before warning letters were issued. It is interesting to note that two of the incidents involved the improper use of malathion by a private citizen. Over the past several years, this type of misuse has occurred often, leading to legislation being introduced by a senator in the current session to make it a felony to "cause harm to human health or the environment" through use of pesticides. As of this writing, the legislation was still pending.

2. Routine Inspections – other than Worker Protection

Forty inspection files were reviewed during the end of year visit, in addition to files that were sent to EPA for enforcement/review. Inspection files were randomly selected from actionable and non-actionable inspections. Inspections selected represented the work of six different inspectors. Inspections continue to document compliance/non compliance with pesticide laws, and in most cases include necessary evidence such as photographs, labels and invoices. It should be noted that by the time the project officer reviews inspection files, they have been reviewed and errors have been corrected by the HI case developer or the inspector. Discussions with the case developer indicate that inspectors, in general, need to continue to pay closer attention to ensuring that reports are clearly written, grammatical errors are corrected, and that reports are "enforcement ready". HDOA forwarded eight inspection files to EPA during FY14 for review and possible enforcement action. Eleven additional files were sent in early FY15. These were forwarded to EPA's enforcement division for review.

There were no Special Requests issued to HDOA during FY14. HDOA did not complete any container/containment inspections, as there are no facilities currently identified in Hawaii that meet the necessary criteria. The Pesticide Container/Containment Inspection and Enforcement Accomplishment Report (EPA C/C Form 5700-33H) is included in Appendix 2.

1. Oversight inspections (non-WPS) - none

C. Compliance Priority – Worker Protection Standard (WPS)

1. Reports

a) The Pesticide Worker Protection Standard Inspection and Enforcement Accomplishment Report (WPS Form 5700-33H) is included in Appendix 3.

2. Significant WPS Cases (FIFRA Section 27) - none

3. WPS oversight inspections – none

4. WPS case file evaluation

HDOA conducted five WPS Tier 1 inspections at establishments throughout Hawaii, continuing a trend down from ten in FY 13, and down from forty in FY12. There were no enforcement actions issued for any Tier 1 inspections conducted in FY14. Five Tier 2 inspections were also conducted, up from two the previous year. HDOA needs to increase WPS inspection numbers throughout Hawaii as recommended in FY13. Inspectors should work towards increasing their numbers of both Tier1 and Tier 2 inspections in the current year.

5. Worker Protection Risk-Based Targeting Strategy

a) Implementation of Risk-Based Targeting Strategy

A WPS targeting strategy was developed in 1994. Targeting was based partly on how many restricted-use pesticides were purchased by growers, as well as how many workers were employed by the establishment. Since that time, agriculture has changed dramatically in Hawaii. The number of large farms with many workers has greatly decreased. Farms are smaller (average farm size is 150 acres) and growers buy smaller quantities of pesticides. Inspectors have found that they can identify establishments that fall under the WPS by conducting routine agricultural use inspections and asking questions related to worker activity during the inspection. They will then return at a later date to conduct a WPS inspection. Larger establishments are inspected approximately every two years.

D. Inspection and Enforcement Support

1. Training

HDOA conducts an annual pesticide training workshop for all HDOA Pesticide Program staff (inspectors, education, and registration staff) and outer Pacific Island pesticide programs in November of each year. The workshop also includes medical monitoring and respirator fit-testing for inspectors. The project officer attends this workshop, in conjunction with the end of year visit. The project officer presented updates from EPA, including revisions to the Worker Protection Standards. The FY14 workshop was designed with training and collaboration in mind. Inspectors spent a full week together, conducting inspections, meeting afterwards to discuss results, and focused on training, report writing and other field exercises.

In FY14, HDOA had six federally-credentialed inspectors. Training records were properly maintained at the Honolulu office, and inspectors had met the commitments outlined in the FIFRA inspector credential authorization agreement. A new inspector was credentialed in August, 2014. It should be noted that the four inspectors, below, need to begin the process to renew their credentials that expire on November 1, 2015. Inspectors should consult EPA's inspector Wiki site at https://wiki.epa.gov/inspector for information on annual refresher requirements for maintaining a federal credential.

Steven Ogata	Credential No. 10093
Lester Chin	Credential No. 10092
Christopher Gerken	Credential No. 10090
Ann Kam	Credential No. 10089

Below is a partial list of training courses attended by HDOA staff in FY14:

TRAINING/MEETING	DATE
Structural PIRT - WA	3/2014
Ag Leadership - DC	4/2014
ALSTAR(Accepted Labels States Tracking and Repository)	4/2014
WRPM - Seattle	5/2014
PIRT for New Inspectors	5/2014
ASPCRO (Structural Conference)	8/2014
ALSTAR/NPIRS Conference	9/2014

2. Enforcement Response Policy

The Hawaii Department of Agriculture revised and adopted its Pesticide Enforcement Action and Penalty Assessment Schedule on October 24th, 2006. Review of case files indicates that HDOA follows its enforcement response policy, however there are numerous areas where the policy is in need of updating. In FY14, The Department of Agriculture completed the task of filling positions on the Governor's Pesticide Advisory Committee, which will take up the issue of revision of pesticide regulations in Hawaii, as well as the enforcement response policy. HDOA is encouraged to continue to identify those areas that are lacking in the ERP, so that at a future date, changes can be made.

3. Neutral Inspection Scheme

Applicators that are likely to use more RUPs are inspected more frequently than those that do not. This is based on amounts of RUPs purchased divided by the number of applicators employed by a business. With regard to marketplace inspections, they are conducted primarily based on complaints, rather than through a neutral inspection scheme. This has been discussed during previous reviews as an area for additional focus by HDOA. HDOA should consider whether these overall approaches to targeting inspections are still appropriate and effective.

4. Inspection and Enforcement Procedures

Discussions were held throughout the year between HI inspection staff and EPA as procedural issues arose. HDOA has revised the Branch Standard Operating Procedures, which includes neutral inspection procedures. HDOA has one case development officer that reviews all files as they come in from the inspection staff. During FY14, HDOA assigned an inspector to assist the case developer in reviewing files. This action was very helpful in working through many files that were old or had no violations. This inspector is currently on maternity leave, but will continue to assist when she returns.

In addition, we reported last year that the more serious cases that lead to civil complaints are sent to the deputy attorney general's office for review and concurrence. The deputy AG's office also has a backlog of civil cases to review, which results in penalty actions not being issued. Currently, there are at least ten civil complaints in the deputy AG's office awaiting review, dating back to 2012. The Pesticide Program has at least 20 additional complaints waiting to be submitted. In early FY14 the Deputy AG's office hired an assistant as well, and while she was very effective, she took another position after only a few months. There are still a large number of civil complaints to be developed at the AG level. Legislation was passed in FY14 to fund an additional case developer for the Pesticides Branch. This position will be filled in FY15.

5. Quality Assurance

HDOA's Pesticide Program QAPP was approved by EPA on February 24, 2014. The Chemical Analysis Laboratory operates a state-of-the-art pesticide residue laboratory for the analysis of a wide range of plant, soil, product and environmental samples in support of enforcement and registration activities. In 2014, the Hawaii Department of Agriculture Laboratory (Lab) participated in the Pesticide Residue Check Sample Program administered by the State of Wisconsin Department of Agriculture. The Lab received soil samples in March 2014 and plant samples in November 2014. Hawaii's results initially came back high for the organophosphates in soil, but it was discovered that there was a miscalculation in the mass of the soil, so it was easily rectified. Results for the fall sampling program were acceptable.

6. Special Activities

In cooperation with EPA, HDOA is providing ongoing support to outer Pacific island pesticide program staff on import, inspection, enforcement, and certification issues. As in previous years, HDOA extended an invitation to outer island inspectors to attend the Inspector Workshop. Attendance at the workshop provided an opportunity for the inspectors to receive medical monitoring exams and respirator fit tests, as well as to participate in mock inspections with fellow inspectors and to receive important training.

In April 2014, HDOA received approval from Governor Abercrombie to develop an Integrated Pesticides Information System within the Pesticides Branch that will include the enforcement, registration and certification programs, as well as the Chemical Analysis Laboratory. Once implemented, this system will allow staff from all programs to coordinate their activities, and will also provide greater access to pesticide information by the public. A demonstration of progress to date was provided during the inspector workshop in November. Several key staff members are involved in the development of this system.

In FY14, HDOA received laboratory funds in the amount of $41,600 from EPA. These funds are provided to states on a rotating basis, and can be used to update equipment needed for pesticide sampling and analysis. HDOA purchase several pieces of equipment with these funds, including a diode-array detector for the liquid chromatograph; liquid chromatograph chem-station upgrade; geno/grinder plant & animal homogenizer, and a nitrogen generator.

HDOA received one-time funding in FY14 in the amount of $8,000 to develop informational booklets with IPM curriculum to be distributed to elementary-age students. The goal was to ensure that the message of IPM is brought home to parents, using, in some cases, Hawaiian words to ensure understanding among family members. This project was started, but has not yet been completed. HDOA plans to use State funds to complete this project.

E. New Legislation and Regulations

One pesticide-related piece of State legislation was passed in FY14. SB 2110 (SD2 HD1) added four new positions for the Pesticide Branch of HDOA. Those positions will include one case developer and three inspectors (for Kauai, Oahu and Hawaii).

F. Action Items from Previous Reviews

Recommendation 10-02: HDOA should review their enforcement penalty policy and identify areas that need revision or update.

Status: This was discussed during the end of year review, and during the FY15 cooperative agreement negotiations. HDOA understands where the penalty policy has weaknesses and/or is problematic, and plans to strengthen this and other parts of HI's pesticide rules in the near future. These changes will require a formal change in Hawaii's Pesticide Law, and must be initiated by the Advisory Committee on Pesticides.

Recommendation 10-03: HDOA should develop a neutral scheme for conducting marketplace inspections. One approach would be to select an EPA priority area (such as products that make public health claims) to create a neutral inspection scheme.
Status: This recommendation remains in effect; HDOA should review its targeting strategies to ensure that they are still effective.

Recommendation 13-01: HDOA must forward inspections to EPA that either 1) were conducted with a Federal credential, or 2) reveal a potential federal violation.
Status: Eight files were sent to the Regional Office during FY14 for review and possible enforcement. This does not reflect all of the inspections that were conducted with a federal credential or that potentially have federal violations. There remains a large backlog of inspection files. This recommendation remains open.

Recommendation 13-02: HDOA has seen a downward trend in overall inspection activity in FY13, especially with regard to WPS Tier 1 inspections. HDOA should make every effort to increase the number of WPS Tier 1 inspections in the coming year.
Status: A downward trend continues for HDOA, as only five WPS Tier 1 inspections were conducted in FY14.

Recommendation 13-03: HDOA should formally request that EPA send the enforcement liaison to the upcoming November workshop at the HI Department of Agriculture. This will ensure that state inspectors are provided the most up-to-date requirements for their work under the cooperative agreement.
Status: HDOA did request that the enforcement liaison attend the inspector workshop. Unfortunately, the EPA enforcement division was not able to send the liaison to the workshop.

Recommendation 13-04: HDOA must identify ways to address the backlog of inspection files, whether through assigning inspection staff to review files or hiring additional case developers. Solutions to the backlog that also exists with cases at the Deputy Attorney General's office must also be identified. (NOTE: At the time of this writing, HDOA had assigned inspection staff to assist in reviewing inspection files, in order to decrease the backlog.)
Status: Having the additional inspector to help with file review has been very helpful to the case developer. When the inspector returns, she will continue to help out with file reviews. Legislation passed in FY14 will also bring a new case development position to the branch.

Recommendation 13-05: HDOA is asked to identify those policies and documents in need of revision and a plan put in place to make the necessary updates. (NOTE: At the

time of this writing, several changes had been put in place, including additional personnel to review inspection files, and the AG's office had also hired an assistant to focus on pesticide civil cases.)
Status: Unfortunately, the deputy AG's office was not able to retain the assistant, so again there is only one attorney currently working on Pesticide cases in that office.

Recommendation 13-06: HDOA should ensure that the POINTS system is updated on a yearly basis, and that progress is made in evaluating pesticides of interest to Hawaii.
Status: POINTS database had not been updated at the time of this writing. HDOA should ensure that the POINTS database is updated.

F. Conclusions and Recommendations for Compliance/Enforcement

EPA continues to have significant concerns with the backlog of inspection files to be processed, and the resulting lack of enforcement actions issued, as well as the lack of inspections forwarded to EPA for review/enforcement.

V. PROGRAMS

A. Worker Safety – C&T

1. Previous Recommendations - none

2. Accomplishments

a) Work-Plan Commitments & National Program Priorities

HDOA had 1058 certified commercial and 317 private applicators at the end of FY14, a total that has decreased by over 100 from FY13. HDOA administered exams and reviewed 180 courses for continuing education units, compared to 199 the previous year. HDOA also provided 19 presentations to certified applicators during the course of the year, down from 37 the year before. Honolulu staff covered exam administration and consultative visits on Oahu, Kauai, Maui and Molokai. The island of Hawaii is covered by an additional employee based in Hilo. Fourteen courses were monitored by HDOA in FY14. Certification reporting in CPARD was completed by HDOA in a timely manner.

HDOA's databases for certified applicators as well as for tracking continuing education units are cumbersome and not integrated. Once implemented, the Integrated Pesticides Information System will allow the Education staff to manage and review courses, track classes, exam results and credits, as well as produce quarterly reports on all certification and training activities. This database will ultimately be an important and timesaving tool for staff.

HDOA worked closely with the Cooperative Extension Service (CES), meeting at least twice per year with representatives from CES Pesticide Applicator Training Program, at the University of Hawaii. HDOA also meets with the Hawaii Pest Control Board, which reviews and approves applications for new pest control businesses in the state. University personnel travel to each of the neighbor islands to prepare applicators in core topics for the certification exam on a yearly basis. The University of HI is currently revising the core exam to make the questions more applicable and connected to the study material that applicators use to prepare for the exam.

Certification cards issued in Hawaii currently have a photo ID and bar code. Annual C&T Plan Reports for Hawaii and other states are available at: http://cpard.wsu.edu/

3. PART Review Measures - none

4. State/Tribe Feedback - none

5. Conclusions and Recommendations

All negotiated outputs have been satisfactorily met for FY14.

B. Worker Safety - WPS

1. Previous Recommendations - none

2. Accomplishments

a) Work-Plan Commitments & National Program Priorities

HDOA conducted 18 WPS training sessions, reaching 73 participants. Eight consultative visits were also held, and are scheduled when a new applicator becomes certified, or, if an applicator has received a notice of warning. A visit may be made to ensure that the applicator has subsequently come into compliance. HDOA is also responding to a recent increase in Chinese and Laotian immigrant farmers on Oahu by providing pesticide safety and WPS training at key locations. HDOA also provided outreach using the updated How to Comply Manual to agricultural establishments. HDOA meets several times per year with the University of Hawaii Cooperative Extension and the Pest Control Board of the Department of Commerce and Consumer Affairs to discuss training and WPS issues. In FY14, HDOA held several Farmer Resource Workshops, designed as a "one stop shop" for farmers to obtain information on a wide range of topics. Topics range from proper pesticide use, agriculture loans and insurance, to soil conservation and air pollution regulations. These workshops have been held on Oahu, Hawaii, Maui and Kauai, and have been well-received.

In FY13, HDOA received special one-time funding to develop a slideshow which would be translated into several languages (Ilocano, Laotian, Mandarin, Cantonese and Tagalog) to provide workers and handlers with pesticide safety information. At the time of this writing, the slideshow was in the editing phase, and near completion in all languages. HDOA hopes to complete this project in FY15 using state funds.

The agricultural landscape in Hawaii has changed from the dominance of sugar cane and pineapple plantations to many small farms where ethnically-diverse owners grow a multitude of minor crops. In FY12, the second highest violation found by HDOA inspectors was application of pesticides to crops not on the label. HDOA received special one-time funding in FY14 in the amount of $45,000 to develop a cross reference of minor crops, including plant identification, synonymous names, related species and crop grouping. The ultimate goal was to assist in locating pesticides registered for use on these crops, if any. Some progress was made on the project, but most of the funding was returned to EPA. HDOA does plan to restart work on the project using state funding.

3. PART Review Measures - none

4. State/Tribe Feedback - none

5. Conclusions and Recommendations

With the exception of the two special projects, all negotiated outputs have been satisfactorily met for FY14.

C. Water Quality

1. Previous Recommendations - none

2. Accomplishments

a) Work-Plan Commitments & National Program Priorities:

At the end of FY14, the Pesticides of Interest Tracking System (POINTS) had not been updated, but it was completed in early 2015. HDOA has evaluated 51 of 73 Pesticides of Interest (70%), is actively managing 16 of 17 Pesticides of Concern (POC; 94%) and is demonstrating progress for 10 of managed POCs (63%). HI evaluated several products for ground water concerns during FY14, including EPTC, cyantraniloprole and cyproconazole, for example. HDOA uses modeling to determine whether new chemicals may have the potential to leach into groundwater. Restricted use pesticide sales records are monitored to identify products that may affect water quality. HDOA has discussions with HI Department of Health (DOH) as well as registrants to discuss pesticides of concern for surface and ground water. The HI Department of Health is responsible for implementing the pesticides NPDES permit program in Hawaii.

3. State/Tribal Concerns - none

4. Conclusions and Recommendations

D. Endangered Species

1. Previous Recommendations - none

2. Accomplishments

a) Work-Plan Commitments & National Program Priorities

HDOA continues to consult and coordinate with other State agencies on Section 18 emergency exemption requests and special local needs registration applications. During FY14, an Endangered Species Act (ESA) Section 7 informal consultation was sent to EPA for four pending SLNs for use of rodenticides in agricultural and forest/other island areas.

3. PART Review Measures - none

4. State/Tribe Feedback – none

5. Conclusions and Recommendations

All negotiated outputs have been satisfactorily met for FY14.

U.S. Environmental Protection Agency

Hawaii Department of Agriculture
FY2015 Final End-of-Year Review

Pesticide Performance Partnership Grant

EXHIBIT 13

Executive Summary- This report covers workplan activities conducted in FY15, and is based on discussions and review of documents throughout the year and during the end of year visit. Recommendations for improvements can be found within the body of this report. Recommendations focus primarily on reducing a large backlog of inspection files that need review and possible case development, securing a backup laboratory if state lab equipment breaks down, and improving inspections and report writing. HDOA must also focus on revising the enforcement response policy, and forwarding more inspection files to EPA for review and/or follow-up. This report covers the first year of a multi-year performance partnership grant (PPG) between Hawaii Department of Agriculture and EPA Region 9. This PPG was put into place to ease administrative burdens on HDOA and to allow for more long-term planning for the HDOA Pesticide Program.

I. BACKGROUND

A. General

1. **Project Period:** October 1, 2014 – September 30, 2015.

2. **EPA Assistance Agreement Number:** #BG00T64415-1

3. **Review method:** On-site

4. **Review participants:**

EPA: Mary Grisier, Hawaii Pesticide Project Officer, Scott McWhorter, EPA FIFRA Inspector/Enforcement Liaison

Grantee: Thomas Matsuda, Pesticide Program Manager, Victoria Matsumura, Case Preparation Officer

5. **Review date(s) and location:** November 16-19, 2015 at the Hawaii Department of Agriculture offices in Honolulu.

B. Scope of Review

The Hawaii Department of Agriculture (HDOA) has primary enforcement responsibility over pesticide use activities in the State of Hawaii and is the lead state agency for the enforcement of the Hawaii Pesticides Law (Chapter 149A, Hawaii Revised Statutes) and Hawaii Administrative Rules (Chapter 66, Title 4). There are approximately 1,150,000 acres in farmland, 7,000 farms, 6,400 agricultural workers, 3,800 Agricultural Operators, 1,200 certified applicators, 22 licensed Restricted Use Pesticide (RUP) dealers, 18 pesticide producing establishments, and seven licensed aerial applicators in the state of Hawaii. Major crops in Hawaii include seed corn, coffee, papaya, macadamia and nursery plants. Average farm size in Hawaii is 150 acres. HDOA maintains a database of all pesticides licensed in Hawaii. The HDOA Pesticide program consists of approximately

14 individuals over 4 islands performing inspection, education, registration, administrative, and other pesticide program activities.

The Hawaii Pesticide program is supported by both State (general and revolving) and federal (USDA and USEPA) funds. HDOA and USEPA Region 9 had one active Performance Partnership Grant (PPG) with pesticide related activities to be carried out in Federal Fiscal Year 2015. The purpose of the PPG is to reduce paperwork and provide administrative relief and flexibility to HDOA. FY15 was the first year of a multi-year agreement.

The FY15 end-of-year evaluation was primarily accomplished by reviewing quarterly reports and correspondence received from HDOA throughout the year, and an on-site visit by the project officer and FIFRA inspector from EPA Region 9. Additionally, the inspector conducted oversight inspections with staff from HDOA. Information gathered was compared to the outputs and standards in the cooperative agreements to determine if HDOA had met its commitments.

II. FINANCIAL

A. Budget Analysis

The following table summarizes funding and expenditures for the FY15 cooperative agreement. In FY15, approximately three FTE were supported by EPA funding (Environmental Health Specialists II & III, Chemist).

Federal Financial Reports (FFRs) for FY15 had not been received at the time of this writing.

Work Plan Component	EPA Funding	Grantee Funding*	Total Funding
Enforcement	$186,200	$34,672	$220,872
Programs	$116,125	$22,038	$138,163
C&T	$ 30,000	$30,255	$ 60,255
Supplemental $	$ 0	$ 0	$0
TOTAL	$332,325	$ 86,965	$419,290

* State is required to provide 50% match in C&T, 15% (by policy) for other programs.

Re-budgeting –Rebudgeting consisted of a $786.00 rescission on the part of EPA.

III. GENERAL GRANT ADMINISTRATION

A. Recommended Actions for Grants Office - None

IV. COMPLIANCE AND ENFORCEMENT

A. Grantee Reports

1. <u>5700-33H</u> report – attached as Appendix 1.

2. Annual Summary of Inspections and Enforcement Actions

HDOA exceeded the number of projected inspections (311 projected, 314 completed). This is approximately 74 fewer inspections conducted than in FY14. HDOA issued four civil complaints in FY15, up from one in FY14. Forty warning letters were issued, and one case was assessed a fine in FY15. There were eleven inspection files referred to EPA for enforcement review and possible development in FY15, up from eight forwarded in FY14. HDOA should continue to forward cases that, for any reason, may present difficulties for the state to pursue.

B. Case File and Enforcement Action Evaluation

1. Significant Cases (FIFRA Section 27)

There were no formal high level episodes referred to HDOA in FY15. However, HDOA saw a significant increase in pesticide-related complaints from individuals and groups throughout the state. Many of these complaints focused on alleged misuse of pesticides by large seed-corn companies, as well as state and local departments of transportation doing roadside weed control. In addition, some complaints centered on HDOA itself, alleging that HDOA does not adequately enforce state and federal regulations. It should be noted that HDOA follows up on every complaint that is received; with essentially one inspector on each island, this level of follow-up has become nearly impossible to maintain, while also attempting to conduct routine, neutral scheme inspections. HDOA is in the process of hiring additional inspectors for Oahu, Kauai and Hawaii islands, as well as an additional case developer for Oahu. HDOA has initiated discussions with state and local transportation departments to ensure that best management practices are being used when roadside spraying occurs. EPA Region 9 is closely monitoring this situation and is in regular contact with HDOA.

2. Routine Inspections

Oversight Inspections Conducted During End of Year Review

Inspectors should follow all inspection procedures for conducting federal inspections, including presenting valid credential (e.g., in one case, a credential was expired), presenting a written notice of inspection describing the reason(s) for inspection (e.g., in one case, a violation was suspected but not identified) and a signed receipt for samples (e.g., in one case, no receipt was given or was missing from the report). Inspectors should routinely collect a similar and adequate amount of documentation for all producer establishment inspections, including taking photographs, photo copies for purchases and sales invoices* and production logs*, maintenance and repair logs (a years' worth), manufacturing or repackaging agreements, labels, and all other relevant FIFRA and RCRA (waste manifests) records. Records sampled and collected should show evidence that they were maintained for a minimum of 2 years in most cases. If information that is routinely collected is unavailable at the time of inspection, this information should be requested for a later date to be sent to the state or in some cases be sent directly to EPA).1 If information routinely collected does not exist, it should be fully documented in the report that this information was requested and it does not exist. If it exists but elsewhere, the inspector must still request this information be sent to either the state or EPA (e.g., in one case, the inspector did not collect information or request that it be sent, instead the inspector took a statement that the information exists but is not maintained at the facility. This is not adequate. All of these issues must be addressed to improve inspections.

Recommendation 15-01: Inspectors should review the *2013 FIFRA Inspector's Manual* and ensure that all inspections follow the requirements for document collection, issuance of appropriate forms and that adequate narratives accompany all inspections.

Inspection Reports Reviewed During End of Year Review
Approximately thirty inspection files were reviewed during the end of year visit, in addition to files that were sent to EPA for enforcement/review. Inspection files were randomly selected from actionable and non-actionable inspections. Inspections selected represented the work of five different inspectors. In general, the report narratives tend to be short. If there is nothing to report, the narrative should explain why a thorough investigation did not occur. When narratives are short, they often lack critical information. It is not clear whether inspectors are not disclosing information, or whether they are not documenting all aspects of the inspection. Specifically for Pesticide Establishment Inspections, inspectors should consult the *2013 FIFRA Inspectors' Manual* and contact EPA for assistance to ensure adequate information is being documented. All of these issues must be addressed to improve inspection report writing.

There were no Special Requests issued to HDOA during FY15. HDOA did not complete any container/containment inspections, as there are no facilities currently identified in Hawaii that meet the necessary criteria. The Pesticide Container/Containment Inspection and Enforcement Accomplishment Report (EPA C/C Form 5700-33H) is included in Appendix 2.

C. Compliance Priority – Worker Protection Standard (WPS)

1. Reports

1 *e.g., purchases, sales, or production records might be identified as FIFRA CBI and should be sent directly to the FIFRA Document Control Officer in Region 9.

a) The Pesticide Worker Protection Standard Inspection and Enforcement Accomplishment Report (WPS Form 5700-33H) is included as Appendix 2.

2. Significant WPS Cases (FIFRA Section 27) - none

3. WPS oversight inspections – EPA Inspector McWhorter conducted one oversight inspection of a WPS Tier 1 inspection during the end of year review.

4. WPS case file evaluation

HDOA conducted seventeen WPS Tier 1 inspections at establishments throughout Hawaii, up from five in FY 14. There were no enforcement actions issued for any Tier 1 inspections conducted in FY15. There were no Tier 2 inspections conducted, while there were five the previous year.

5. Worker Protection Risk-Based Targeting Strategy

a) Implementation of Risk-Based Targeting Strategy

A WPS targeting strategy was developed in 1994. Targeting was based partly on how many restricted-use pesticides were purchased by growers, as well as how many workers were employed by the establishment. Since that time, agriculture has changed dramatically in Hawaii. The number of large farms with many workers has greatly decreased. Farms are smaller (average farm size is 150 acres) and growers buy smaller quantities of pesticides. Inspectors have found that they can identify establishments that fall under the WPS by conducting routine agricultural use inspections and asking questions related to worker activity during the inspection. They will then return at a later date to conduct a WPS inspection. Larger establishments are inspected approximately every two years.

D. Inspection and Enforcement Support

1. Training

HDOA conducts semi-annual pesticide training workshops for all HDOA Pesticide Program staff (inspectors, education, and registration staff) and outer Pacific Island pesticide programs in May and November of each year. The workshop in November also includes medical monitoring and respirator fit-testing for inspectors. In 2015, the project officer and the EPA inspector attended the November workshop, in conjunction with the end of year visit. The EPA inspector presented updates from EPA, including enforcement priorities and highlights from the revised worker protection standards. Federal Enforcement priorities for Hawaii include Worker Protection Tier 1 inspections, Product Integrity (including taking more samples during inspections), and the ongoing compliance monitoring of basil farmers in Hawaii.

In FY15, HDOA had four federally-credentialed inspectors. Training records were properly maintained at the Honolulu office, and inspectors had met the commitments outlined in the FIFRA inspector credential authorization agreement. All four credentials expired on November 1, 2015. As of this writing, EPA is in the process of issuing new credentials.

Below is a partial list of training courses attended by HDOA staff in FY15:

TRAINING/MEETING	DATE
Executive Lab PREP, GA	4/2015
Pollinator PREP, OR	5/2015
FIFRA Pesticide Analyst Workshop, OK	5/2015
Registration PREP, VA	7/2015
C&T PACT Workshop, PA	8/2015
ASPCRO Annual Mtg, FL	8/2015
ALSTAR/NPIRS Conference, NV	9/2015

2. Enforcement Response Policy

The Hawaii Department of Agriculture revised and adopted its Pesticide Enforcement Action and Penalty Assessment Schedule on October 24th, 2006. Review of case files indicates that HDOA follows its enforcement response policy, however there are numerous areas where the policy is in need of updating. In FY14, the Department of Agriculture was able to fill several positions on the Governor's Pesticide Advisory Committee, which has responsibility for revision of pesticide regulations in Hawaii, as well as revising the enforcement response policy. HDOA is encouraged to continue to identify those areas that are lacking in the ERP, so that at a future date, changes can be made.

3. Neutral Inspection Scheme

Applicators that are likely to use more RUPs are inspected more frequently than those that do not. This is based on amounts of RUPs purchased divided by the number of applicators employed by a business. With regard to marketplace inspections, they are conducted primarily based on complaints, rather than through a neutral inspection scheme. This has been discussed during previous reviews as an area for additional focus by HDOA. HDOA should consider whether these overall approaches to targeting inspections are still appropriate and effective.

4. Enforcement Procedures

Since at least 2012, there has been a large backlog of inspection files to be reviewed by enforcement staff. At the time of the end of year review, there were approximately 700 inspection files in need of review, some dating back to 2008. This is a major concern, and has resulted in delays for both state and federal enforcement proceedings. Federal inspection reports should be referred to EPA at least quarterly per the cooperative agreement. Recent receipt of reports for inspections that occurred as early as 2012 were not received until 2015. Many of these cases were referred to EPA for enforcement action but were closed solely based on our statute of limitations. Also since at least 2012, there has been a large number of proposed enforcement actions that remain with the State deputy attorney general (AG) for review and concurrence. This is very concerning given the large number of complaints drafted (i.e., in the hundreds) versus the small amount of enforcement actions taken (i.e., one for a penalty in 2015). Cases must be reviewed and concluded in a timely and appropriate manner. EPA should be alerted when new cases are being forwarded to the AG that are not being reviewed in timely manner. For high priority cases they should be elevated to EPA for review to determine the appropriate enforcement response (e.g., a Notice of Warning might be adequate). For most of FY15, HDOA had two case development officers that reviewed all files as they came in from the inspection staff. In late FY15, a new deputy attorney general was assigned to pesticide cases in Hawaii. By the end of FY15, four civil actions had been reviewed by the deputy, and then issued by HDOA.

Recommendation 15-02: The process for reviewing inspection files, and developing and ultimately issuing civil actions must be improved. Inspection reports that may present difficulties for HDOA should be forwarded to EPA.

5. Quality Assurance

HDOA's Pesticide Program Quality Assurance Program Plan (QAPP) was approved by EPA on February 24, 2014. Major components of the QAPP include program responsibilities, sampling design, methods and sample handling. The Chemical Analysis Laboratory (CAL) in Hawaii operates a state-of-the-art pesticide residue laboratory for the analysis of a wide range of plant, soil, product and environmental samples in support of enforcement and registration activities. In FY15, the CAL participated in EPA's check sample program, running 136 tests on 10 samples provided by EPA. Analysis results were satisfactory for both soil and vegetation samples. In FY15, the CAL developed a list of pesticides to test for residues in Hawaii bees and honey.
It should be noted that the laboratory experienced significant down time of its LC/MS equipment during FY15. Delays in sample analysis can negatively impact the timeliness of enforcement cases, and also create frustration for individuals who believe that they may have been impacted by pesticide drift.

Recommendation 15-03: HDOA should identify a back-up laboratory that can assist with sample analysis should equipment failures occur in the future. EPA has had discussions with HDOA on this issue, and HDOA has initiated contact with the CA Department of Food and Agriculture laboratory.

6. Special Activities

HDOA continues to consult and coordinate with other State agencies on Section 18 emergency exemption requests and special local needs registration applications. Two experimental use permit applications were pending in the fourth quarter.

Outer Pacific Island Support - In cooperation with EPA, HDOA is providing ongoing support to outer Pacific island pesticide program staff on import, inspection, enforcement, and certification issues. As in previous years, HDOA extended an invitation to outer island inspectors to attend the Inspector Workshops. Attendance at the workshops provided an opportunity for the inspectors to receive medical monitoring exams and respirator fit tests, as well as to participate in mock inspections with fellow inspectors and to receive important training.

Kauai Joint Fact Finding Taskforce – In December 2014, a process was begun to examine possible health and environmental impacts associated with the use of pesticides applied to genetically-modified agricultural products. The County of Kauai and the HI Department of Agriculture were partners in the project by providing funding support and collaborating with the state and the consultant throughout the process. A draft of the findings was released in March 2016.

Integrated Pesticides Information System - In April 2014, HDOA received approval from then-Governor Abercrombie to develop an Integrated Pesticides Information System within the Pesticides Branch that will include the enforcement, registration and certification programs, as well as the Chemical Analysis Laboratory. Once implemented, this system will allow staff from all programs to coordinate their activities, and will also provide greater access to pesticide information by the public. A demonstration of progress to date was provided by the contractor during the inspector workshop in November, and great progress has been made in developing this system. Several key staff members are involved in the development of this system, and when completed, it will provide needed coordination between programs within the Pesticides Branch.

Online Reporting of RUP Sales – As a result of Act 105, passed in FY13, HDOA is required to post RUP sales on a monthly basis. The posting provides a summary of all sales, not broken down by purchaser. On April 1, 2015, HDOA posted the sales records by month by County in pounds of active ingredients for all of 2014.

E. New Legislation and Regulations

Eight bills were introduced in the Hawaii Legislature relating to pesticides during FY15, but none were passed.

F. Action Items from Previous Reviews

Recommendation 10-02: HDOA should review their enforcement penalty policy and identify areas that need revision or update.

Status: HDOA has identified elements of the penalty policy that are in need of revision. Revising the penalty policy will require a formal change in Hawaii's Pesticide Law. The current process for revising the policy requires assistance from a pesticide advisory committee, whose members are appointed by the Chairperson. HDOA should make every effort to streamline this process and revise deficiencies in the pesticide penalty policy.

Recommendation 13-01: HDOA must forward inspections to EPA that either 1) were conducted with a Federal credential, or 2) reveal a potential federal violation.
Status: Eleven files were sent to the Regional Office during FY15 for review and possible enforcement. This does not reflect all of the inspections that were conducted with a federal credential or that potentially have federal violations. There remains a large backlog of inspection files. This recommendation remains open.

Recommendation 13-02: HDOA has seen a downward trend in overall inspection activity in FY13, especially with regard to WPS Tier 1 inspections. HDOA should make every effort to increase the number of WPS Tier 1 inspections in the coming year.
Status: HDOA has improved inspection numbers, particularly as it relates to WPS, Seventeen WPS Tier 1 inspections were conducted, up from five in FY14. This recommendation is closed.

Recommendation 13-03: HDOA should formally request that EPA send the enforcement liaison to the upcoming November workshop at the HI Department of Agriculture. This will ensure that state inspectors are provided the most up-to-date requirements for their work under the cooperative agreement.
Status: The EPA inspector was able to attend the FY15 November workshop, and he also participated in oversight inspections with HDOA inspectors. He provided information regarding EPA enforcement priorities and other assistance to inspectors. This recommendation is closed.

Recommendation 13-04: HDOA must identify ways to address the backlog of inspection files, whether through assigning inspection staff to review files or hiring additional case developers. Solutions to the backlog that also exists with cases at the Deputy Attorney General's office must also be identified.
Status: The backlog of inspection files continues to be an issue for HDOA. Steps have been taken to decrease the backlog using a temporary position, as well as having inspectors help review inspection files for actionable violations. In February 2016, the senior case developer retired, leaving one full-time case developer in the Branch. The number of inspection files will continue to grow, however, and HDOA should put every effort into hiring an additional case developer. This recommendation remains open.

Recommendation 13-05: HDOA is asked to identify those policies and documents in need of revision and a plan put in place to make the necessary updates.
Status: In particular, the enforcement penalty policy is in need of revision. This recommendation remains open.

Recommendation 13-06: HDOA should ensure that the POINTS system is updated on a yearly basis, and that progress is made in evaluating pesticides of interest to Hawaii. **Status:** The POINTS database has been updated for FY15. This recommendation is closed.

F. Conclusions and Recommendations for Compliance/Enforcement

EPA continues to have significant concerns with the backlog of inspection files to be processed, and the resulting lack of enforcement actions issued. More inspections should be forwarded to EPA for review/enforcement. HDOA should work with EPA's inspector to make improvements to inspections and report writing. HDOA should ensure that the enforcement penalty policy is revised and strengthened. A backup laboratory should be identified to assist if HDOA's lab equipment has breakdowns.

V. PROGRAMS

A. Worker Safety – C&T

1. Previous Recommendations - none

2. Accomplishments

a) Work-Plan Commitments & National Program Priorities

HDOA had 1092 certified commercial and 297 private applicators at the end of FY15. HDOA administered exams and reviewed 167 courses for continuing education units, compared to 180 the previous year. HDOA also provided 5 presentations to certified applicators during the course of the year, down from 19 the year before. The education program at HDOA lost one staff member during the 3rd quarter of FY15. Honolulu staff covered exam administration and consultative visits on Oahu, Kauai, Maui and Molokai. The island of Hawaii is covered by an additional employee based in Hilo. Fifteen courses were monitored by HDOA in FY15. Certification reporting in CPARD was completed by HDOA in a timely manner.

HDOA's databases for certified applicators as well as for tracking continuing education units are cumbersome and not integrated. Once implemented, the Integrated Pesticides Information System will allow the Education staff to manage and review courses, track classes, exam results and credits, as well as produce quarterly reports on all certification and training activities. This database will ultimately be an important and timesaving tool for staff.

HDOA worked closely with the Cooperative Extension Service (CES), meeting at least twice per year with representatives from CES Pesticide Applicator Training Program, at the University of Hawaii. HDOA also meets with the Hawaii Pest Control Board, which reviews and approves applications for new pest control businesses in the state. University personnel travel to each of the neighbor islands to prepare applicators in core topics for the certification exam on a yearly basis.

Certification cards issued in Hawaii currently have a photo ID and bar code. Annual C&T Plan Reports for Hawaii and other states are available at: http://cpard.wsu.edu/

3. Conclusions and Recommendations

All negotiated outputs have been satisfactorily met for FY15.

B. Worker Safety - WPS

1. Previous Recommendations - none

2. Accomplishments

a) Work-Plan Commitments & National Program Priorities

HDOA conducted 17 WPS training sessions, reaching 129 participants. Seven consultative visits were also held; these are scheduled when a new applicator becomes certified, or, if an applicator has received a notice of warning. A visit may be made to ensure that the applicator has subsequently come into compliance. HDOA is also responding to a recent increase in immigrant farmers on Oahu by providing pesticide safety and WPS training at key locations. HDOA also provided outreach using the updated How to Comply Manual to agricultural establishments. HDOA meets several times per year with the University of Hawaii Cooperative Extension and the Pest Control Board of the Department of Commerce and Consumer Affairs to discuss training and WPS issues.

The agricultural landscape in Hawaii has changed from the dominance of sugar cane and pineapple plantations to many small farms where ethnically-diverse owners grow a multitude of minor crops. This has resulted in farmers who are unaware of or unable to understand pesticide product labels, as well as those who may understand but choose not to comply with labels, as seen with several basil farmers in Hawaii. Education staff at HDOA is working on a project to develop visual identification cards for crop/pest identification, which will go online in the future, and will ultimately be available in multiple languages.

3. Conclusions and Recommendations

All negotiated outputs have been satisfactorily met for FY15.

C. Water Quality

1. Previous Recommendations - none

2. Accomplishments

a) Work-Plan Commitments & National Program Priorities:

The HDOA Pesticides of Interest Tracking System (POINTS) system was updated for FY15. HDOA has evaluated 53 of 79 Pesticides of Interest (79%), is actively managing

17 of 18 Pesticides of Concern (POC; 94%) and is demonstrating progress for 10 of 17 managed POCs (59%). HDOA evaluated several products for ground water concerns during FY15, including, cyantraniloprole and flupyradifurone. It was determined that both must be licensed as restricted use pesticides. HDOA uses modeling to determine whether new chemicals may have the potential to leach into groundwater. Restricted use pesticide sales records are monitored to identify products that may affect water quality. DOH is responsible for implementing the pesticides NPDES permit program in Hawaii.

3. Conclusions and Recommendations

All negotiated outputs have been satisfactorily met for FY15.

D. Endangered Species

1. Previous Recommendations - none

2. Accomplishments

a) Work-Plan Commitments & National Program Priorities

No formal reviews were requested in FY15.

3. Conclusions and Recommendations

All negotiated outputs have been satisfactorily met for FY15.

DAVID Y. IGE
Governor

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Lt. Governor

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August 3, 2015

VIA EMAIL (alec.wong@doh.hawaii.gov)

Mr. Alec Wong, P.E., Chief
State of Hawaii
Department of Health
Clean Water Branch
P.O. Box 3378
Honolulu, Hawaii 96801-3378

Dear Mr. Wong:

Subject: National Pollutant Discharge Elimination System (NPDES) Permit
Agribusiness Development Corporation
Kekaha, Island of Kauai, Hawaii
Permit No. HI0000086

Thank you for your letter dated July 7, 2015, granting the Agribusiness Development Corporation (ADC) an extension of time within which to either withdraw its permit application or to continue to pursue its NPDES permit renewal. Thank you also to you, Mr. Kawaoka, and the Clean Water Branch staff for meeting with the ADC on July 31, 2015 to discuss ADC's existing permit and anticipated compliance problems, and its nonpoint source pollution options.

After much investigation, the ADC does not anticipate that it will be able to comply with the Water Quality Standards which will be incorporated into a renewed NPDES permit. Accordingly, the ADC would like to withdraw its application to renew Permit No. HI0000086.

The ADC is committed to developing a monitoring and management plan, and incorporating the best management practices possible, to address the nonpoint pollution runoff in Kekaha. As discussed at our recent meeting, in addition to naturally-occurring additions to the ADC's irrigation water, there are a number of stakeholders whose operations are dependent upon the ADC receiving their waters which are then mixed with the ADC's irrigation water before exiting into the ocean. The ADC has already opened discussions with several of these stakeholders concerning the problems associated with this combined runoff. The ADC has also begun its review of several of

EXHIBIT 7
EXHIBIT 14

its tenants' individual soil conservation plans. The ADC would therefore like to be the initial point of contact for the management plan in the area.

The ADC would appreciate any guidance and assistance your office might provide in the development of a management plan that is custom-designed to address the runoff in Kekaha. We will be proposing an agreement, of sorts, between our agencies to delineate exactly how a management plan should be developed, and what it should address and include. Also, as an attached governmental agency, we are interested in pursuing any federal grant for which the ADC might qualify to help defray the costs of such a plan. We look forward to working with you and your staff on this endeavor.

Sincerely,

for James J. Nakatani
Executive Director

cc: Keith Kawaoka (keith.kawaoka@doh.hawaii.gov)
Marianne Rossio (Marianne.rossio@doh.hawaii.gov)
Ted Bohlen (edward.g.bohlen@hawaii.gov)
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Landis Ignacio (ignacio@hawaii.rr.com)

To: Mccarthy, Gina[McCarthy.Gina@epa.gov]
Cc: Tom Vilsack (Agsec@usda.gov)[Agsec@usda.gov]
From: James Callan
Sent: Wed 4/13/2016 1:21:14 PM
Subject: Letter on Scientific Advisory Panel - Request for Postponement
Stakeholders Letter to Administrator McCarthy.pdf

Dear Administrator McCarthy:

I am sending the attached letter on behalf of 42 organizations representing U.S. agriculture and users of crop protection tools and pest control products. These organizations are deeply concerned about EPA's planned Scientific Advisory Panel (SAP) meeting, April 19 to 21, to change the long-accepted, science-based regulatory endpoint for the pesticide chlorpyrifos and ask you to postpone this hastily called meeting.

Thank you for your attention to this important matter, and I look forward to sharing your response with the affected groups.

Sincerely,

-James Callan

James Callan Associates LLC

jamescallan@msn.com

703.577.1978 – mobile

www.jamescallanassociates.com

April 13, 2016

The Honorable Gina McCarthy
Administrator
U.S. Environmental Protection Agency
Sent via email: McCarthy.Gina@epa.gov

Dear Administrator McCarthy:

As organizations representing U.S. agriculture and users of crop protection tools and pest control products, we are deeply concerned about EPA's planned Scientific Advisory Panel (SAP) meeting, April 19 to 21, to change the long-accepted, science-based regulatory endpoint for the pesticide chlorpyrifos, and we ask you to postpone this hastily called meeting.

Chlorpyrifos is a widely-used and widely-tested chemistry proven to be safe and effective for an array of commodities, specialty crops, and public health uses throughout the United States.

With this hasty and rushed SAP, EPA is attempting to fundamentally alter its process for evaluating potential risk and regulation of pesticides. EPA is moving forward as if the current regulatory process developed over four decades is broken. Recognizing the abruptness of this shift in approach and potential impact to all pesticides, the standards to be met for such a change should be set high. The failure to adhere to policies and regulations, reliance on a single epidemiological study for which the Agency does not even possess the underlying data, and lack of a solid basis for the most fundamental assumptions, do not meet such a high scientific or policy standard.

This not only would adversely affect chlorpyrifos; it also sets a terrible precedent for other organophosphates and pesticides. This also comes at a time when America's production agriculture is facing low commodity prices and strained budgets. If EPA proceeds with this European-style precautionary approach not based on sound scientific principles, we are going to lose valuable crop protection tools. Unfortunately, this path would have a chilling effect on the ability of companies to bring new and improved products to market—an objective sought by EPA—and further harm producers' ability to protect crops and compete in domestic and international markets.

We respectfully ask you to postpone the SAP until there is appropriate attention given to the scientific validity of the underlying assumptions for this dramatic change in how pesticides are regulated. Not only are there scientific questions, but only days have been given to review what the Agency has prepared and distributed to SAP members and the public.

Our organizations believe that the Agency's lack of transparency is a violation of established EPA processes for review of products under the Federal Insecticide, Fungicide & Rodenticide Act (FIFRA). Within FIFRA, EPA also is required to review the best available data. In the process involving chlorpyrifos, the Agency has fallen woefully short of statutory requirements and as stakeholders we expect a consistent and scientific approach based on the law.

We look forward to your response.

Sincerely,

Agricultural Retailers Association
Almond Hullers & Processors Association
American Farm Bureau Federation
AmericanHort
American Soybean Association
American Society of Sugar Beet Technologists
American Sugarbeet Growers Association
Beet Sugar Development Foundation
California Citrus Mutual
California Citrus Quality Council
California Cotton Ginners Association
California Cotton Growers Association
California Date Commission
California Dried Plum Board
California Fig Advisory Board
California Fresh Fruit Association
California Specialty Crops Council
California Strawberry Commission
California Walnut Commission
Cranberry Institute
CropLife America
Florida Fruit & Vegetable Association
Golf Course Superintendents Association of America
National Agricultural Aviation Association
National Association of State Departments of Agriculture
National Association of Wheat Growers
National Corn Growers Association
National Cotton Council
National Council of Farmer Cooperatives
National Pest Management Association
National Potato Council
National Sorghum Producers
North American Blueberry Council
Northwest Horticultural Council
Sunsweet Growers Inc.
United Fresh Produce Association
U.S. Apple Association
Valley Fig Growers
Washington Friends of Farms & Forests
Washington State Potato Commission
Western Agricultural Processors Association
Western Growers Association

cc: Secretary Tom Vilsack
Jason Furman, Chairman of the Council of Economic Advisers
Jeffrey Zients, Director of the National Economic Council
Christy Goldfuss, Managing Director, White House Council on Environmental Quality
Chairman Pat Roberts
Senator Debbie Stabenow
Chairman Michael Conaway
Congressman Collin Peterson

Exponent®

REPORT TITLE

Refined Aggregate Exposure and Risk Assessment for Chlorpyrifos

EPA GUIDELINE(s)

NA

AUTHORS

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PROJECT I.D.

1305765.000 - 2053

REPORT DATE

June 4, 2014

SPONSOR

Dow AgroSciences
9330 Zionsville Rd.
Indianapolis, IN 46268

STATEMENT OF NO DATA CONFIDENTIALITY CLAIMS

No claim of confidentiality, on any basis whatsoever, is made for any information contained in this document. I acknowledge that information not designated as within the scope of FIFRA sec. 10(d)(1)(A), (B) or (C) and which pertains to a registered or previously registered pesticide is not entitled to confidential treatment and may be released to the public, subject to the provisions regarding disclosure to multinational entities under FIFRA 10(g). This statement supersedes any other statement of confidentiality that may appear in this report.

Company: Dow AgroSciences

Company Agent: George Oliver, Ph.D

Title: Regulatory Manager

Signature: George Oliver   Date: 6/3/2014

This report is the property of Dow AgroSciences, and as such, is considered to be confidential for all purposes other than compliance with FIFRA Section 10. Submission of this report in compliance with FIFRA does not constitute a waiver of any right to confidentiality, which may exist under any other statute or in any other country.

GOOD LABORATORY PRACTICE COMPLIANCE STATEMENT

This report is a review of publicly available data. As such, Good Laboratory Practices are not applicable.

Author: ______________________ Date: 6/4/14

Richard Reiss, Sc.D.
Exponent

Contents

List of Tables

List of Figures

Executive Summary

In 2011, the U.S. Environmental Protection Agency (EPA) released a preliminary risk assessment for chlorpyrifos that found risks of concern for drinking water exposures (U.S. EPA, 2011a,b). The drinking water exposures exceeded EPA's levels of concern by as much as 2700%. Normally, EPA combines food, drinking water and other exposures into an aggregate risk assessment, but it declined to conduct an aggregate risk assessment because it determined that other pathways would not significantly add to the drinking water risks. This report provides a refined aggregate risk assessment for chlorpyrifos using more realistic estimates of drinking water exposures. Specifically, instead of modeling estimated concentrations, a large dataset of surface water concentration measurements in the U.S. was used to establish a conservative estimate of the drinking water concentration distribution for chlorpyrifos.

The revised risk assessment shows that drinking water exposures are only a fraction of exposures from food and that food and water exposures are below EPA's toxicity benchmarks. Further, the revised drinking water and food exposure estimates are consistent with a large dataset of a urinary metabolite of chlorpyrifos exposure, which adds confidence in the reliability of the exposure estimates.

To estimate drinking water concentrations for risk assessment, EPA utilizes the PRZM/EXAMS modeling system with an "index reservoir" scenario that is meant to simulate conditions in a small watershed vulnerable to pesticide contamination. The index reservoir is modeled after the Shipman Reservoir in Illinois, which serves about 365 people. The index reservoir watershed area is 172.8 ha. Among the many conservative assumptions with the index reservoir, perhaps the most important is that a large portion of the watershed is assumed to be applied with the same pesticide on the same crop on exactly the same days over a 30-year simulation. In some cases, adjustments are made for the percent cropped area (PCA) treated, which helps somewhat to reduce the conservatism of the assessment. However, because chlorpyrifos has turf uses, EPA, per policy, did not make this adjustment.

Several studies have compared EPA modeling predictions with the index reservoir to concentrations measured in the environment (Winchell and Snyder 2014; Jackson et al. 2005, Echeverria et al. 2012). The median overprediction was about 280-fold (Winchell and Snyder, 2014). The modeling estimates for chlorpyrifos are no exception. The highest measured chlorpyrifos concentration in a review of nationwide monitoring studies was 0.57 ppb, while the modeling estimates were as high as >100 ppb. EPA often states that monitoring programs miss the peak concentrations; however, in a following section we demonstrate that the maximum monitored concentration for >30,000 samples is lower than half of the EPA's annual average modeling estimates.

Another conservative aspect of EPA's assessment is that it assumes that all chlorpyrifos is converted during chlorination to the more toxic chlorpyrifos-oxon in drinking water systems. Further, EPA assumes that there is no dissipation of chlorpyrifos before chlorination or dissipation of chlorpyrifos-oxon after chlorination. The Dow AgroSciences comments on the 2011 preliminary risk assessment detail several processes that could reduce chlorpyrifos and chlorpyrifos-oxon concentrations in the treatment and distribution systems, including adsorption onto particles, removal by activated carbon, and alkaline hydrolysis.

To provide a more reliable basis for estimating drinking water concentrations, the available nationwide water monitoring databases were reviewed. The largest datasets are the United States Geological Survey's (USGS's) National Water Quality Assessment (NAWQA) and National Stream Quality Accounting Network (NASQAN) programs. There are more than 30,000 chlorpyrifos and chlorpyrifos-oxon measurements since 1992 and many samples are taken in locations vulnerable to pesticide contamination. From a statistical analysis by Mosquin et al. (2011) and updated by Mosquin (2014), a distribution of drinking water concentrations was developed.

The analysis by Mosquin provides estimates of the upper-percentiles of the chlorpyrifos drinking water concentration distribution using survey sampling statistical techniques. Mosquin estimated the 95^{th}, 99^{th}, and 99.9^{th} percentiles of the distribution to be 0.0066, 0.0214, and 0.0852 ppb, respectively. Mosquin also estimated upper-bounds on the estimates to be 0.0073 ppb (95^{th}), 0.0244 (99^{th}), and 0.1516 (99.9^{th}) ppb. Both the central tendency and the upper-bound estimates were used to construct distributions of drinking water concentrations for entry into the DEEM-FCID model. Additionally, to avoid any potential underestimation, additional distributions were constructed that estimated concentrations above the 99.9^{th} percentile using the maximum measured concentration of 0.57 ppb. The mean value of the distribution was used for the chronic analysis, conservatively using the half of the limit of quantification in the dataset of for non-detects (0.0025 ppb).

The EPA dietary and drinking risk assessment was reproduced and upgraded to the new version of DEEM, which led to exposures from drinking water that were generally the same or lower than those from the old version of DEEM. For example, the value mentioned above of 2700% from the old version of DEEM was only 2300% in the new version of DEEM. DEEM-FCID was then rerun using the drinking water distributions described above for acute risk analysis and the average value from the Mosquin analysis for the chronic analysis. To account for the conversion of chlorpyrifos and chlorpyrifos-oxon, toxicity adjustment factors (TAFs) need to be applied. Both the values used by EPA (12 for acute and 18 for chronic) and recommended by Dow (7 for acute and 2.7 for chronic) were used.

For the water only analysis, the acute exposures were no more than 1.7% of the acute Population Adjusted Dose (aPAD) using the most extreme distribution from the monitoring data. Using the base scenario with the central tendency estimate from Mosquin, the exposure was no more than 1.2% of the aPAD. These values are substantially lower than EPA's estimates.

For the food plus water analysis, the exposures are no more than 12.3% of the aPAD and 13.2% of the cPAD. Using the base scenario with the EPA TAFs, the exposures were no more than 12.0% of the aPAD and 13.2% of the cPAD. The TAF assumption did not significantly affect the final results because most of the exposure was to the parent in food. This analysis shows there are no risks of concern using the refined estimates for drinking water exposure.

The results of the analysis were validated using biomonitoring data. The chlorpyrifos metabolite, 3,5,6-trichloro-2-pyridinol (TCP_y), was measured in urine of more than 5,000 subjects in the National Health and Nutrition Examination Survey (NHANES) study. The TCP_y data can be used to estimate chlorpyrifos exposures after making assumptions for creatinine, TCP_y directly ingested in food, and the fraction of chlorpyrifos metabolized to TCP_y. These estimates can be used to estimate a distribution of exposures in the population. The estimated exposures from TCP_y agree quite closely with EPA's food only estimates and the food plus drinking water exposure estimates presented in this report. The agreement lends confidence to the validity of the estimates. However, EPA's water only estimates vastly exceed the exposure estimates back-calculated from TCP_y, suggesting that the EPA water only exposures are overestimated, likely substantially so. While it is possible that there are very small groups of people that may experience higher drinking water concentrations than captured by NHANES, it is not apparent in any of the drinking water monitoring data, which shows only very low concentrations or non-detects.

An aggregate assessment was also performed, including golf course and ULV mosquito uses. Dow is not supporting these uses, but they were included for completeness because EPA has indicated that it will include them in the revised risk assessment. When the golf courses uses were included, the aggregate assessment had Margins of Exposure (MOEs) greater than the goal of 100, indicating no risk concerns. For the mosquito uses, the MOEs were less than the goal of 100, except for adults and ground applications. Nonetheless, the aggregate assessment with the mosquito uses had far higher MOEs than if the EPA drinking water modeling estimates were used.

Introduction

In June of 2011, the U.S. Environmental Protection Agency (EPA) released the document entitled "Chlorpyrifos: preliminary human health risk assessment for registration review (U.S. EPA 2011a). A companion EPA document (2011b) was also released and included a detailed dietary and drinking water exposure and risk assessment for chlorpyrifos. The current document presents a refined dietary and drinking water risk assessment.

The dietary risk assessment was performed using EPA's standard methodologies, including the use of the Dietary Exposure Evaluation Model DEEM-FCID. DEEM-FCID estimates dietary exposures probabilistically using data on food consumption and chlorpyrifos residue levels on food commodities. For both acute and chronic exposures, the dietary risk estimates for food only exposures were well below EPA's level of concern.

EPA decided not to rely on the extensive drinking water monitoring data available for chlorpyrifos, but instead used a theoretical modeling tool to estimate water concentrations in a small reservoir. EPA also assumed that all chlorpyrifos in the drinking water system was converted to the more toxic chlorpyrifos-oxon. The estimated drinking water concentrations with EPA's modeling tool are far higher than any measured concentrations in either surface water or finished drinking water. EPA modeled a number of scenarios, including what it described as lower-end (sugar beets), mid-range (corn), and higher-end (grapes). Within each of these categories, EPA modeled typical and maximum application rates.

EPA's acute drinking water exposure estimates exceeded the acute Population Adjusted Dose (aPAD) and chronic Population Adjusted Dose (cPAD), sometimes by wide margins. The highest acute exposure estimate was 13.415 μg/kg-bw/day [micrograms per kilogram body weight per day] for grapes at the maximum application rate, which was 27-fold over the aPAD of 0.5 μg/kg-bw/day for chlorpyrifos-oxon. The highest chronic exposure estimate was 0.974 μg/kg-bw/day for grapes at the maximum application rate. The estimated exposure was 9-fold over the cPAD of 0.11 μg/kg-bw/day for chlorpyrifos-oxon.

EPA did not perform an aggregate risk assessment because it determined that the residential exposures would not significantly add to the drinking water exposures. The EPA preliminary risk assessment discusses an ultra-low volume (ULV) mosquito use and a golf course use as being part of a future aggregate risk assessment. Dow AgroSciences (Dow) has indicated that it is no longer supporting these uses; however, other chlorpyrifos labels include these uses so they are considered in this assessment. EPA has also indicated that it may include spray drift and volatilization into aggregate risk assessments in the future; however, it has not developed specific guidance for doing so. Therefore, for this assessment, only exposures from food, drinking water, mosquito control uses, and golf course uses are considered in the aggregate assessment.

In this report, an alternative and more reliable method is used to estimate drinking water concentrations. Specifically, the extensive surface water and drinking water monitoring data for chlorpyrifos were reviewed. The largest database is for surface water concentrations in the National Water Quality Assessment (NAWQA) and National Stream Quality Accounting Network (NASQAN) programs from the United States Geological Survey (USGS). From this extensive dataset, the distribution of drinking water concentrations was estimated. This distribution can be used in DEEM-FCID in place of EPA's theoretical modeling estimates to refine the dietary risk assessment.

The dietary risk assessment can be validated with the use of biomonitoring data. The National Health and Nutrition Examination Survey (NHANES) included urinary measurements of the chlorpyrifos metabolite 3,5,6-trichloro-2-pyridinol (TCP_y) from 1999 to 2002 for over 4,000 subjects. From these data, the true distribution of chlorpyrifos exposures in the population can be characterized and compared with the dietary exposure estimates.

Background

Description of EPA's 2011 Assessment

In 2011, EPA released the Health Effects Division's (HED) preliminary human health risk assessment for chlorpyrifos (U.S. EPA, 2011a,b). Chlorpyrifos was being evaluated under the FIFRA section 3(g) registration review program which requires the re-evaluation of pesticides on a 15 year cycle. The preliminary assessment was provided in support of the registration review process for chlorpyrifos.

The EPA Environmental Fate and Effects Division (EFED) provided chlorpyrifos-oxon estimated drinking water concentrations (EDWCs) for chlorpyrifos use on grapes, corn/soybean and sugar beets. These estimates were intended to provide a range of possible EDWCs representing the many registered chlorpyrifos uses. The Agency reviewed currently available monitoring data, but concluded that it likely underestimated chlorpyrifos and chlorpyrifos-oxon concentrations because the data were limited and may not have captured peak concentrations. For these reasons, monitoring data were not used in the preliminary assessment.

Refined acute and chronic dietary (food and water) exposure and risk assessments were conducted for chlorpyrifos. The United States Department of Agriculture (USDA) Pesticide Data Program (PDP) monitoring data were used for most foods. Empirical study-based processing factors were used. Because there are turf uses for chlorpyrifos (including golf courses), EPA did not use Percent Cropped Area (PCA) factors per its policy.

For food alone, the preliminary acute dietary risk estimates for all populations assessed were below the level of concern. For water alone (using the chlorpyrifos-oxon PoD), the preliminary acute risk estimates using the lower-end representative water scenario (sugar beets) were below the level of concern for all populations assessed at the maximum application rate except for infants at 210% aPAD. At the average typical rates for sugar beets, exposures were also of concern for infants (340% aPAD), and children (130-140% cPAD). Using the mid-range representative scenario (corn), the acute risk estimates for all populations assessed were above the level of concern for the maximum application rates; the risk estimate for the most highly exposed subpopulation, infants, was 770% aPAD. However, for typical application rates, the risk estimates were much lower (<120% aPAD) for all populations assessed. Using the higher-end representative water scenario (grapes), the acute risk estimates were below the level of concern for all populations assessed at the typical application rates (<59% aPAD for infants), but were above the level of concern at the maximum application rates assessed (2700% aPAD for infants).

The preliminary chronic dietary risk estimates (food alone) for all populations assessed were below the level of concern. For water alone (using the chlorpyrifos-oxon PoD), the preliminary chronic risk estimates spanned a large range, depending on the representative crop and application rate assessed. Using the lower-end representative water scenario (sugar beets), risks were below the level of concern for all populations assessed based on the maximum application rates (<69% cPAD); however, there were some risks of concern for typical rates assessed for infants and children (110-270% cPAD). Drinking water risk estimates for the mid-range and higher-end representative water scenarios (corn and grapes) were below the level of concern at the typical application rates (<49% cPAD) for the highest exposed subpopulation, infants (<1 yr), but exceeded the level of concern at the maximum application rates (ranged from 280-890% cPAD) for infants (<1 yr).

A quantitative aggregate (food, water and residential exposures combined) assessment was not performed for the preliminary chlorpyrifos assessment. The Agency's preliminary risk estimates for water alone exceeded the level of concern and were therefore considered the primary driver in the assessment. It was concluded that combining food and/or residential exposures with the water exposures would not have a significant impact on the resulting risk estimates for water alone. The Agency indicated that they would consider an aggregate assessment during the final chlorpyrifos risk assessment. As noted, the uses that EPA was considering for the aggregate assessment, the ULV mosquito and golf course uses, are no longer being supported by Dow.

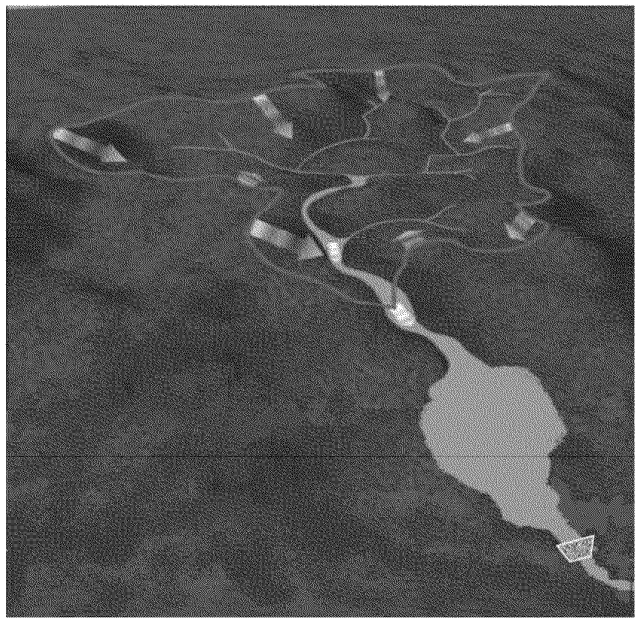
Sources of Overestimates in EPA's Drinking Water Exposure Assessment

EPA estimates drinking water concentrations using a theoretical modeling methodology. The basis for the methodology is what is termed the "index reservoir," which is intended to represent a small, vulnerable reservoir and is based on the Shipman Reservoir in Illinois (Jones et al. 2010). The Shipman Reservoir serves about 365 people.

EPA uses a simple screening model, FIRST, for Tier 1 assessments. For chlorpyrifos, EPA used its Tier 2 modeling procedure. In Tier 2, runoff and spray drift into the reservoir are modeled using the Pesticide Root Zone Model (PRZM) and partitioning and dissipation within the water column are modeled using the Exposure Analysis Modeling System (EXAMS). EPA assumes the concentration estimates in the index reservoir as the influent to the drinking water system. It assumes that all chlorpyrifos is oxidized to chlorpyrifos-oxon in the treatment system and that there is no further dissipation of chlorpyrifos-oxon.

Figure 1 shows a conceptual model of the index reservoir. The reservoir has a 5.3 ha area and is approximately 82 m wide and 640 m long. The depth is assumed to be 2.74 m with a 5 cm thick benthos. As shown in Figure 1, the reservoir is fed by a variety of streams, some of which are perennial and some ephemeral. The watershed area is 172.8 ha and is assumed to have 2200 m^2 of perennial streams and 3800 m^2 of ephemeral streams.

Figure 1. Conceptual model of EPA index reservoir (Jones et al. 2010)



Jones et al. (1998) details the parameters used in the index reservoir, including dispersive parameters, sediment properties, external environment, location, biological characterization, water quality, and reservoir temperature. Different fractions of the applied mass are assumed as spray drift into the reservoir depending on the type of application, with higher spray drift for aerial applications than airblast or ground applications.

Besides representing a very small and vulnerable scenario, one of the most conservative assumptions with the index reservoir modeling is the PCA factors. The scenario assumes that a large portion of the watershed area is applied with the same pesticide on the same crop and on exactly the same day every year throughout a 30-year scenario. If multiple applications of pesticide are allowed in a year, all applications are assumed to be on the same days for every year of the simulation.

EPA only allows the applied area of the watershed to be adjusted by the PCA (Echeverria et al. 2012). The PCA is intended to account for the percent of the watershed area that is treated with a crop-pesticide combination. However, EPA conducted a nationwide search to identify the highest possible PCAs and then apply these values to the highly vulnerable Shipman Reservoir.

This combination of upper-bound assumptions results in an unrealistic scenario. As Winchell and Snyder (2014) detail, the PCA factors are unrealistically large (e.g., 0.33 for cotton, 0.61 for corn, 0.91 for "other agricultural land"), which results in the assumption that applications of the same pesticide occur throughout the watershed, often a majority of the area, on the same day. As Winchell and Snyder (2014) state:

> "This assumption is inappropriate for even the smallest sized watersheds that can support an adequate drinking water supply (such as the 172.8 ha Shipman Reservoir) and has greater invalidity as the size of the CWS [community water system] watershed increases and the variability of agronomic practices of multiple farms contributes to a broad range in pesticide application dates. Accounting for the variability in application timing when modeling pesticide fate and transport at the watershed scale has been shown to have a significant effect on predicted concentrations in flowing water bodies."

For chlorpyrifos, EPA did not apply a PCA factor because there are turf uses. The lack of any adjustment for the treated area further exacerbates the potential for overestimation of exposure.

Other conservative assumptions in the drinking water modeling include:

- The PRZM model also does not account for a number of factors that reduce runoff, including vegetative buffer strips.
- Assumption that all treated fields are adjacent to water bodies and all water bodies are downwind of the treated fields, thus maximizing spray drift.
- Use of only a single soil that is vulnerable to runoff.
- Use of upper-bound values for key environmental fate parameters.

Winchell and Snyder (2014) reviewed studies comparing EPA index reservoir model predictions with actual water monitoring data and found that the median overprediction was about 280-fold. One the studies reviewed by Winchell and Snyder (2014) was Jackson et al. (2005). In this study, index reservoir estimates were compared with data from a USGS and EPA pilot monitoring study of finished drinking water in 1999 and 2000 for 25 pesticides. The pilot monitoring program focused on small reservoirs with relatively large amounts of pesticide use. Table 1 summarizes the results. The index scenario substantially overpredicted measured drinking water concentrations for all pesticides. The overprediction ratio averaged 1,240 and ranged from 4 (picloram) to 17,532 (tebuthiuron).

Other studies, including Echeverria et al. (2012) have reached similar findings.

Table 1. Comparison of index reservoir-predicted drinking water concentrations and measured drinking water concentrations from USGS pilot drinking water monitoring study

Pesticide	Highest Index Reservoir Modeled Concentration (ppb)	USGS Pilot Drinking Water Study, Maximum Concentration (ppb)	Overprediction Ratio
2,4-D	145	0.634	229
2,4-DB	140	0.054	2593
Acifluorfen	13.4	0.062	216
Aldicarb	98.7	<0.082	>1,204
Atrazine	438	11.6	38
Benomyl	9.34	0.22	42
Bentazon	32.5	0.34	96
Bromoxynil	88.3	0.057	1,549
Clopyralid	15.8	0.17	93
Dicamba	32.5	0.19	171
Flumetsulam	2.25	0.088	26
Imazaquin	3.09	0.35	9
Imazethapyr	3.06	0.13	24
Linuron	35	0.035	1000
MCPA	81	0.12	675
Metalaxyl	101	0.35	289
Methomyl	16.3	<0.077	>212
Nicosulfuron	1.92	0.14	14
Norfluazon	215	0.41	524
Oryzalin	161	0.13	1,238
Picloram	5.27	1.44	4
Propiconazole	125	0.064	1,953
Sulfometuron-methyl	1.87	0.16	12
Tebuthiuron	1350	0.077	17,532
Terbacil	125	0.10	1,250

Another conservative aspect of EPA's risk assessment is the assumption that all chlorpyrifos is converted to chlorpyrifos-oxon during chlorination disinfection, and that there is no dissipation of chlorpyrifos before chlorination or chlorpyrifos-oxon after chlorination in the drinking water system. In Dow's comments to the 2011 risk assessment, it detailed various processes that could result in the reduction of chlorpyrifos and/or chlorpyrifos-oxon in drinking water systems, including:

- Adsorption onto particles in the treatment system.
- Removal by activated carbon in gravity filtration systems.
- Alkaline hydrolysis in the distribution system. Alkaline hydrolysis is particularly rapid for the oxon. Also, OCl-, present from chlorine disinfection, assists the hydrolysis of the oxon.

Therefore, even if all chlorpyrifos converts to chlorpyrifos-oxon, there is likely a loss of chlorpyrifos-oxon in the drinking treatment and distribution system.

In sum, the conservative assumptions in EPA's modeling result in unrealistic and greatly overestimated drinking water concentrations, which skew the overall dietary risk assessment. In reality, the food exposures are likely higher than the drinking water exposures, but the EPA assessment finds that drinking water exposures vastly exceed food exposures. This report provides a more realistic assessment of dietary risks using actual monitoring data.

Review of Water Monitoring Data

Summary of Available Data

There is a large amount of water monitoring data for chlorpyrifos, both in finished drinking water and in surface waters that are potential drinking water sources. There is also groundwater data, but given the physicochemical properties of chlorpyrifos, any potential occurrence is more likely in surface water contamination than groundwater. Therefore, the focus here is on surface water. The Dow comments on the preliminary risk assessment details much of these data (Dow AgroSciences, 2011). These data are sufficient to characterize chlorpyrifos concentrations in drinking water. This analysis considers the largest nationwide monitoring programs, including:

- OP registrant study of finished drinking water in vulnerable community water systems (CWSs) (Tierney et al. 2001).
- United States Department of Agriculture Pesticide Data Program (PDP).
- USGS NAWQA program of streams, rivers and reservoirs.
- USGS NASQAN program of larger rivers.

These data are reviewed below.

Tierney et al. (2001)

Organophosphate (OP) insecticide registrants conducted a targeted monitoring study more than a decade ago, when chlorpyrifos uses were higher and when there were still residential uses, of finished drinking water in 27 community water systems (CWSs) influenced by agricultural runoff and 17 CWSs influenced by urban runoff (Tierney et al. 2001). The CWSs were selected based on proprietary usage data from the registrants. The study included both chlorpyrifos and chlorpyrifos-oxon and the limit of quantification (LOQ) for both compounds was 0.05 ppb and the limit of detection (LOD) was 0.0089 ppb for chlorpyrifos and 0.0070 ppb for chlorpyrifos-oxon.

Weekly samples were collected during each insecticide's high use period and monthly samples were collected during the remainder of the year. There were no detections of chlorpyrifos or chlorpyrifos-oxon in any of the samples, including 731 finished drinking water samples from the 27 agricultural runoff-influenced CWSs and from 372 finished drinking water samples from the 17 urban-influenced CWSs.

Pesticide Data Program

Monitoring data in the USDA PDP (PDP) dataset has been ignored in the current drinking water estimates for the dietary assessment. Based on a review of the PDP dataset from 2001 to 2012, chlorpyrifos and its oxon have never been observed in water at the consumer level. The monitoring data set contains 8,993 samples analyzed for chlorpyrifos and chlorpyrifos oxon. No detections have been observed over the last decade-plus for chlorpyrifos or chlorpyrifos oxon. Table 2 below provides information on the types and number of samples analyzed.

Table 2. Summary of 2001 to 2012 PDP data for Chlorpyrifos and Chlorpyrifos oxon in drinking water

Analyte Form	Listed Sample Type	Samples Analyzed (N)	Detections (N)
Chlorpyrifos			
	Bottled Water	745	0
	Drinking Water	1741	0
	Finished	1619	0
	Groundwater	800	0
	Untreated	1641	0
Chlorpyrifos-oxon			
	Untreated	723	0
	Drinking Water	1024	0
	Finished	700	0
Total from 2001 to 2012		8993	0

The EFED rationale for not including the PDP data stresses (1) that the sampling program has not been designed to capture an acute daily peak and (2) that as a national survey it is not automatically representative of all regional watersheds. However, the consistency of the dataset over time is not being taken into account. The dataset indicates that year-on-year sampling identifies no detectable concentrations of chlorpyrifos or chlorpyrifos oxon, which provides assurance that chlorpyrifos contamination of drinking water is not a public health issue.

NAWQA

The United States Geological Survey (USGS) implemented the NAWQA in 1991[1]. There were originally 51 study units. Beginning in 2002, nine units were discontinued. During intensive periods, sampling is generally conducted on a biweekly basis.

All data for chlorpyrifos and chlorpyrifos-oxon were downloaded from the NAWQA site for the years 1991 through 2013 (last year available). The long-term minimum detection limit (LT-MDL) ranged from 0.018 to 0.005 ppb throughout the period, with the lower value being applicable since October of 2010. Values below the LT-MDL are also reported as "estimated" and described as "information rich" or "semi-quantitative." To be conservative, these values are included in the summaries provided in this section.

Table 3 summarizes summary statistics for chlorpyrifos and chlorpyrifos-oxon surface water concentrations from 1991 to 2013. For chlorpyrifos, there were 31,397 samples with 4,407 detects (14% detection rate). The average value for the detections was 0.015 ppb and the maximum detected value is 0.57 ppb. A fuller discussion of the distribution of this dataset is provided later. For chlorpyrifos-oxon, there were 8,767 samples with only 19 detects. All detections were "estimated" values. The detection rate was 0.2%, the average detection was 0.021 ppb, and the maximum detection was 0.054 ppb.

Table 3. Summary statistics of chlorpyrifos and chlorpyrifos-oxon surface water measurements in the NAWQA program from 1991 to 2013

Parameter	Chlorpyrifos	Chlorpyrifos-Oxon
Number of Samples	31397	8767
Number of Detects	4407	19
Detection Rate	14%	0.2%
Average Value of Detection (ppb)	0.015	0.021
Maximum Detection Value (ppb)	0.57	0.054

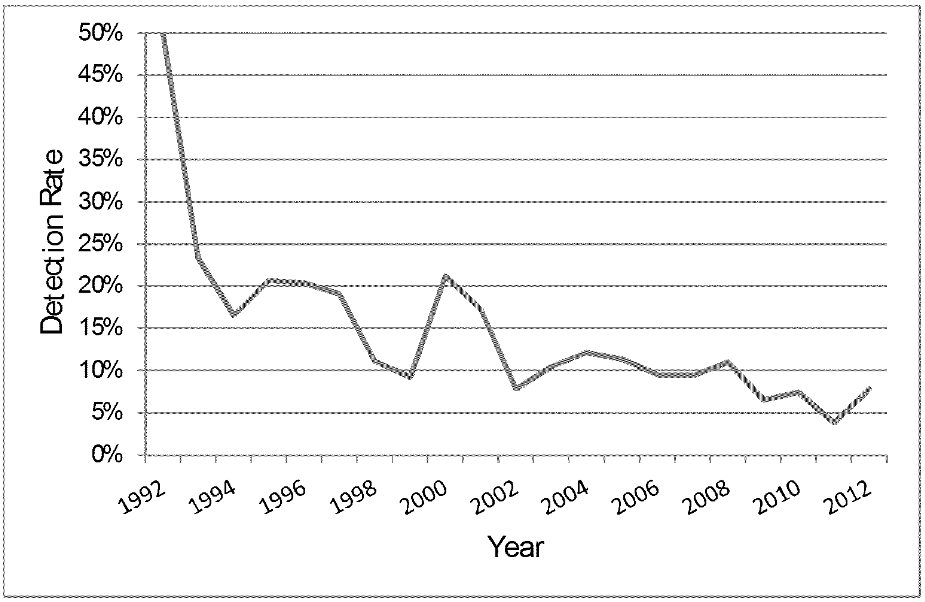
Figure 2 provides the detection rate by year for the chlorpyrifos NAWQA surface water data. There are insufficient detections to perform the same analysis for chlorpyrifos-oxon. The first (1991) and last (2013) years are omitted due to a small number of samples. The detection rate is has clearly declined over time (Figure 2). In 1992, the detection rate was about 50%. In 2000, the rate was above 20%. Since that time, the residential uses have been phased out and the

[1] See program description here: http://water.usgs.gov/nawqa/.

detection rate has declined to below 10%. It is noted that, in this analysis, the annual detection rate may be influenced by the particular sites monitored in a year. Nonetheless, looking at the dataset in totality with over 30,000 samples, it is clear that there has been a significant decline in the chlorpyrifos detection rate.

From 1998 to 2009, NAWQA also includes 363 measurements of chlorpyrifos in finished drinking water. There were no detections.

Figure 2. Annual detection rate for chlorpyrifos in surface water in the NAWQA dataset from 1992 to 2012



NASQAN

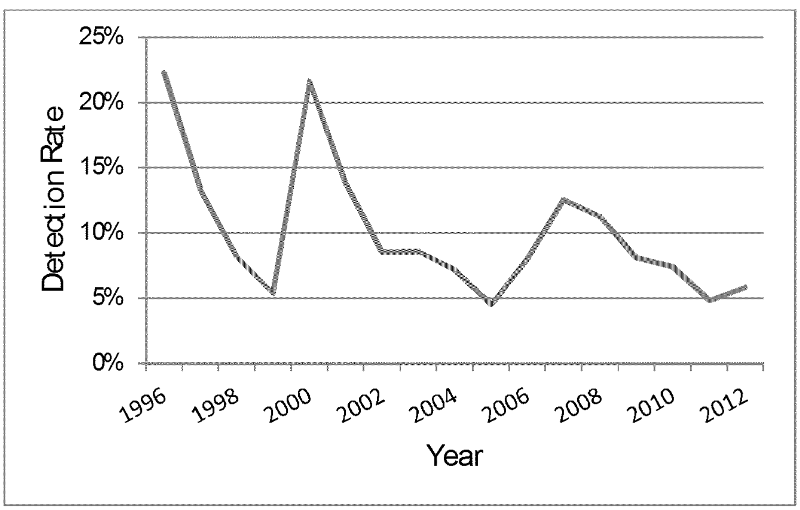
The USGS NASQAN provides water monitoring data at 33 stations throughout the U.S. While NAWQA is focused on smaller rivers and streams, NASQAN focuses on large rivers. The samples are analyzed the same as in the NAWQA program. Table 4 summarizes the chlorpyrifos and chlorpyrifos-oxon detections in the program from 1995 to 2014. The detection rate for chlorpyrifos was 10%. The average detected value was 0.0084 ppb and the maximum detected value was 0.13 ppb. There were only eight detections for chlorpyrifos-oxon and all were "estimated" values. The detection rate was 0.4% and the maximum detected value was 0.036 ppb.

Figure 3 shows the detection rate by year in the NASQAN dataset. There are insufficient detections to perform the same trend analysis for chlorpyrifos-oxon. In 1996 and 2000, the detection rate was above 20%. In more recent years, the detection rate is consistently below 10%.

Table 4. Summary statistics of chlorpyrifos and chlorpyrifos-oxon surface water measurements in the NASQAN program from 1995 to 2014

Parameter	Chlorpyrifos (ppb)	Chlorpyrifos-oxon (ppb)
Number of Samples	5235	2022
Number of Detects	523	8
Detection Rate	10%	0.4%
Average Value of Detection (ppb)	0.0084	0.017
Maximum Detection Value (ppb)	0.13	0.036

Figure 3. Annual detection rate for chlorpyrifos in surface water in the NASQAN dataset from 1996 to 2012



Summary of Monitoring Data

These monitoring data show that chlorpyrifos concentrations in surface water are always in the sub-ppb range and often much lower. The highest monitoring concentration of 0.57 ppb in the NAWQA program is lower than all of EPA's peak modeling concentration estimates assuming typical rates (ranged from 2.8 to 14.4 ppb) or maximum rates (10.0 to 107 ppb). EPA's highest model estimate is nearly 200-fold higher than the maximum concentration detected in a nationwide data of >30,000 samples. Even half of EPA's annual average concentrations, which range from 0.25 to 9.4 ppb, are higher than the maximum concentration detected in a nationwide data of >30,000 samples. EPA often proposes that monitoring programs miss the peak concentrations, but there is clearly no reason for a modeling methodology to estimate annual average concentrations that are higher than the highest concentration in a monitoring program with greater than 30,000 samples.

Chlorpyrifos and chlorpyrifos-oxon are not detected in finished drinking water samples.

Estimation of Drinking Water Exposure Distribution

Mosquin et al. (2011) developed a statistical methodology to estimate the upper percentiles (90th to 99.9th) of the distribution of chlorpyrifos concentrations in the combined NAWQA and NASQAN databases. Mosquin updated the analysis in 2014 and these values are used in the analysis (Mosquin, personal communication). The methodology by Mosquin has also been applied to atrazine and published in a peer-reviewed journal (Mosquin et al., 2012). Data from 1992 to 2011 were used in the revised analysis. Only data from fixed-frequency sampling sites were used and there needed to be at least one sample in each quarter of the year for a given site to be included. The final dataset included 13,018 samples. While finished drinking water data are also available from PDP, the NAWQA and NASQAN datasets are substantially larger and thus provide the only reasonable basis for reliably estimating the upper percentiles of the distribution. Mosquin et al. (2011) also accounted for the unequal representation of sample days within sample years using an "unequal weighting effect" factor. After applying the factor, the effective sample size was reduced to 8,704.

Mosquin et al. (2011) estimated the concentration percentiles using the svyquantile function in the R programming language (Lumley 2011). This survey-weighted approach accounts for the unequal probability design, including the varying frequency of data collection within years, by weighting data points by how long it was since the previous and next measurement. The methodology also allows an estimate of the 95th upper percentile bound of each concentration percentile estimate.

Mosquin et al. (2011) reported estimates for the 95th, 99th, and 99.9th percentiles. Additional percentiles were provided to Exponent (Mosquin, personal communication, 2014). The estimated percentiles are shown in Table 5. The central estimate for the 90th, 95th, 99th, and 99.9th percentiles are 0.0050, 0.0066, 0.0214, and 0.0852, respectively. The 99.9th percentile estimate is far below the water modeling estimates derived by EPA, as expected given the large discrepancy between the water monitoring measurements and water modeling estimates. The confidence bounds are tight for percentiles up to 99.8th. At the 99.9th percentile, the upper-bound estimate is nearly twice the central estimate. Mosquin et al. (2011) applied a censoring limit of 0.005 ppb in the analysis, consistent with the detection rate and the limit of quantitation (LOQ) in the dataset.

Table 5. Estimated chlorpyrifos concentration percentiles and upper-bound estimates from survey-weighted methodology using NAWQA and NASQAN data

Percentile	Central Estimate (ppb)	Upper Bound (ppb)
90	0.0050	0.0050
95	0.0066	0.0073
96	0.0080	0.0090
97	0.0105	0.0117
98	0.0148	0.0168
99	0.0214	0.0244
99.1	0.0225	0.0265
99.2	0.0244	0.0290
99.3	0.0270	0.0318
99.4	0.0290	0.0330
99.5	0.0322	0.0398
99.6	0.0360	0.0460
99.7	0.0450	0.0595
99.8	0.0604	0.0813
99.9	0.0852	0.1516

The percentile estimates are plotted in Figure 4 with a cubic spline interpolation. The cubic spline interpolation was performed using the *spline* function in R (R Core Team, 2013). The cubic spline provides a good fit for the estimates. Figure 5 shows the upper confidence limit estimates.

A full distribution of water concentration values was simulated for modeling with DEEM-FCID using both the central estimate values and the upper confidence limit values. One hundred thousand random numbers between 0 and 1 were generated in R. For concentrations at or above the 90th percentile (random numbers at 0.9 or above), the *spline* function was utilized to select the value along the distribution. Below the 90th percentile, half of the censoring limit of 0.005 ppb was assumed. Above the 99.9th percentile, the value is extrapolated with the spline function and is somewhat less than the maximum measured value in the water monitoring database. For the acute dietary risk assessment, it is assumed that estimates above the 99.9th percentile will not significantly affect the final result, which is a 99.9th percentile estimate of the food plus water exposure. The reason is that the 99.9th percentile exposure would come as the unlikely result of a hypothetical individual with relatively high consumption of food commodities with high residues plus possibly high consumption of drinking water. Therefore, the 99.9^{th} percentile exposure is likely to be driven by a water concentration on the upper end of the drinking water, but still below the 99.9^{th} percentile. Nonetheless, sensitivity analyses are performed in the dietary modeling section to test and validate this assumption and ensure all potential scenarios are considered.

In addition to the distribution using the central tendency values from Mosquin, a distribution was developed from the upper-bound values from Mosquin.

As Mosquin et al. (2011) explains, there is sufficient sample size in the NAWQA dataset to characterize the distribution only up to the 99.9^{th} percentile. As explained above, it is not necessary to do so because the 99.9^{th} percentile exposure in DEEM is not likely to be affected by a water concentration value above the 99.9^{th} percentile. Nonetheless, to assure that the most extreme values in the water concentration dataset are included in the analysis, a sensitivity analysis will be conducted by performing a linear extrapolation between the estimated 99.9^{th} percentile in the revised Mosquin analysis and the maximum measured value in the NAWQA dataset of 0.57 ppb. Thus, when sampling from the distribution, values above the 99.9^{th} percentile are computed as a linear interpolation (i.e., a straight line) between the 99.9^{th} percentile estimate and the maximum measured value. This procedure was conducted for both the central tendency and upper-bound chlorpyrifos distributions from Mosquin (2014).

Figure 4. Estimated chlorpyrifos surface water concentrations above the 90th percentile with cubic spline interpolation

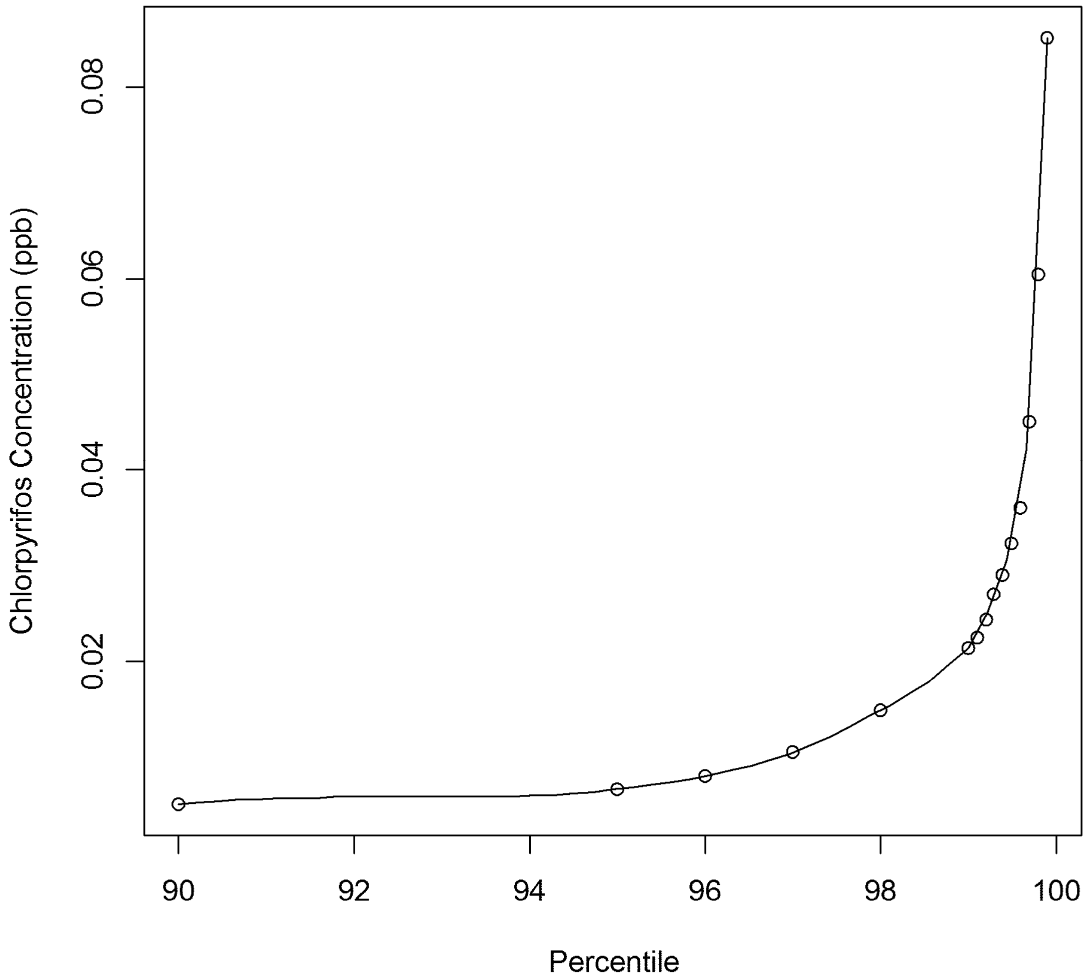
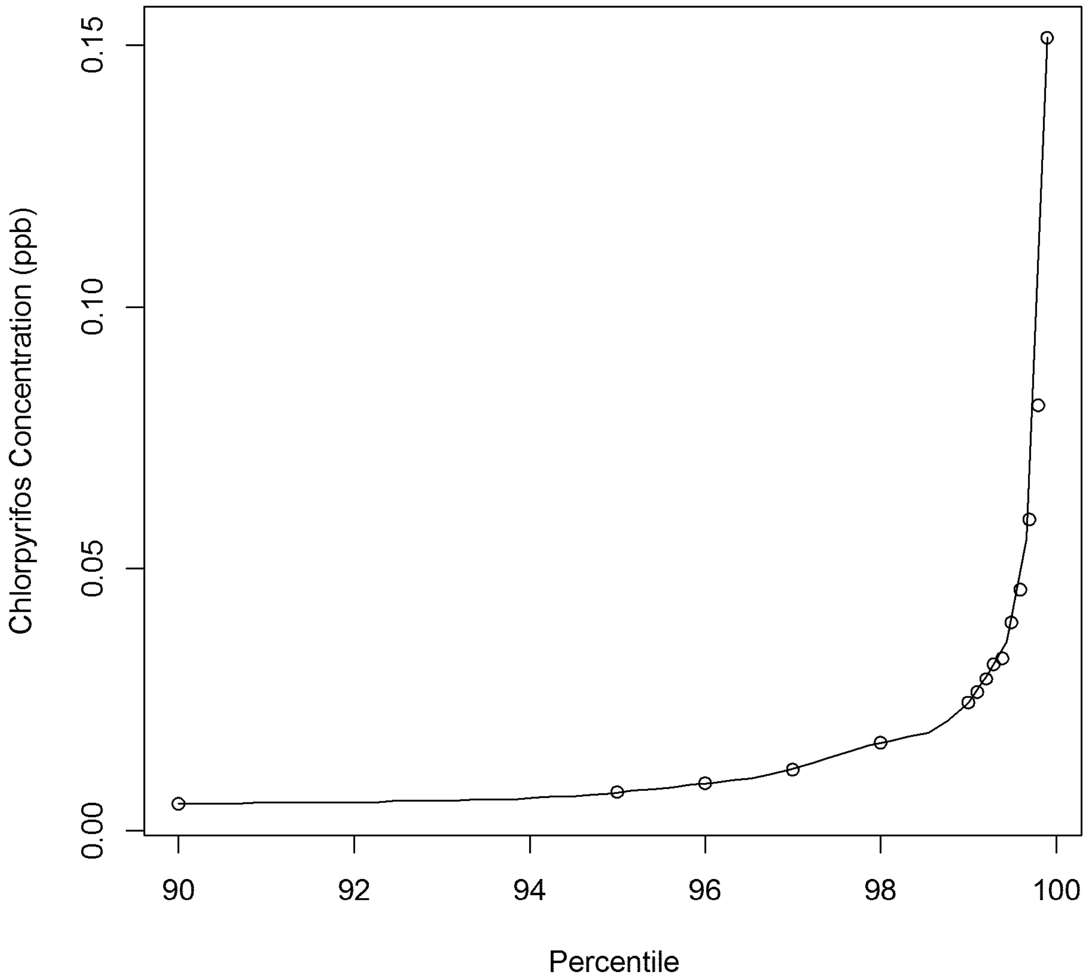


Figure 5. Estimated upper-bound chlorpyrifos surface water concentrations above the 90th percentile with cubic spline interpolation



To summarize, four distributions were developed:

- *Central tendency*: Uses Mosquin (2014) central tendency estimates at or above 90th percentile and half of the censoring limit of 0.005 ppb below 90th percentile.

- *Upper-bound*: Uses Mosquin (2014) upper-bound estimates at or above 90th percentile and half of the censoring limit of 0.005 ppb below 90th percentile.

- *Central tendency with extrapolation >99.9th percentile*: Uses Mosquin (2014) central tendency estimates at or above 90th percentile, censoring limit of 0.005 ppb below 90th percentile, and linear extrapolation between 99.9th percentile and maximum measured value between 99.9th and 100th percentile.

- *Upper-bound with extrapolation >99.9th percentile*: Uses Mosquin (2014) upper-bound estimates at or above 90th percentile, censoring limit of 0.005 ppb below 90th percentile, and linear extrapolation between 99.9th percentile and maximum measured value between 99.9th and 100th percentile.

For the chronic exposure estimate, DEEM-FCID only requires a mean drinking water concentration. The average value from the base scenario distribution was used, conservatively using half of the censoring limit of 0.005 ppb for non-detects. This provides a conservative estimate of the mean drinking water concentration.

It is important to note that by using data from 1992 onward, the distributions above likely overestimate current concentrations. The trend analysis in the last section shows a dramatic reduction in chlorpyrifos detections in surface water since that time.

Dietary Risk Assessment

Reproduction of EPA's Dietary Assessment

The starting point for the dietary assessment was EPA's 2011 assessment (U.S. EPA, 2011a,b). The acute and chronic residue input files from the 2011 EPA assessment were obtained. Although the EPA assessment was conducted recently, it needs further updating in part because EPA has since switched from DEEM version 2.16 (which relies on food consumption data from 1994-1998 collected in the USDA Continuing Survey of Food Intakes by Individuals or CSFII) to DEEM version 3.16 (which relies on food consumption data from 2003-2008 collected in the "What We Eat in America" component of the National Health and Nutrition Examination Survey or NHANES). In order to verify that the input files that were received would produce the same results as in EPA's 2011 assessment, we evaluated the acute and chronic residue files using the original version of DEEM and were able to reproduce the results. The residue files were then converted to the newer version before water monitoring results were added and analyzed with the up to date version of DEEM. Representative input and output files for the acute and chronic dietary assessments are presented in Appendix 1.

Revised Dietary Assessment with Drinking Water Monitoring Data

The first step in modifying the drinking water concentrations in the dietary assessment is to select the toxicity adjustment factors (TAFs) that are used to convert exposure of the oxon in drinking water to an equivalent basis of exposure as the parent in food. Both the TAF values used by EPA in 2011 assessment (U.S. EPA, 2011a,b) and the values recommended by Dow were used (Dow AgroSciences, 2011). For acute exposures, EPA used the TAF value of 12 while Dow recommended a TAF value of 7. For chronic exposures, EPA used a TAF value of 18, while the Dow recommended a TAF value of 2.7.

For dietary exposures to chlorpyrifos from food and water, the TAF values were applied to the water monitoring data estimates (for direct and indirect sources) in order to make the conservative assumption that all of the chlorpyrifos oxidized to form the chlorpyrifos-oxon during the drinking water treatment process. The population adjusted doses (PAD) that were used in this assessment were obtained from EPA's 2011 assessment (U.S. EPA, 2011a,b). Exposures to chlorpyrifos from water alone were compared to the acute and chronic PAD for chlorpyrifos-oxon (0.0005 and 0.00011 mg/kg/day, respectively), because all chlorpyrifos was assumed to be converted to chlorpyrifos-oxon in the drinking water system. Dietary exposures to chlorpyrifos from food and water were compared to the acute and chronic PAD for chlorpyrifos (0.0036 and 0.0003 mg/kg/day, respectively).

Table 6 presents the acute drinking water exposure estimates for the four distribution assumptions discussed earlier. Table 7 presents the exposures for food and drinking water combined. Both tables show the %aPAD for each exposure estimate. For the water monitoring base scenario with central tendency estimates of concentrations, acute exposure to chlorpyrifos (water alone) were estimated to be 0.006 µg/kg/day at the 99.9th percentile for infants (the most highly exposed subpopulation) and 0.002 µg/kg/day for the general population. Expressed as a percent of the aPAD, these exposure estimates are 1.17% for infants and 0.39% for the general U.S. population. For the remaining distributions, acute exposures to chlorpyrifos (water alone) were estimated to range from 0.006 to 0.009 µg/kg/day at the 99.9th percentile for infants (the most highly exposed subpopulation) and from 0.002 to 0.003 µg/kg/day for the general population. Expressed as a percent of the aPAD, these exposure estimates are 1.28% to 1.71% for infants and 0.49% to 0.66% for the general U.S. population. Acute exposures below 100% of the aPAD are reasonably anticipated to result in no harm to exposed populations.

Table 6. Acute exposures and % of aPAD using estimates from water monitoring data alone

Population Subgroup	Base Scenario with Central Tendency Estimates of Concentrations	Upper-Bound Estimates of Concentration	Central Tendency Estimates with Extrapolation Past 99.9th Percentile	Upper-Bound Estimates with Extrapolation Past 99.9th Percentile
	Exposure (µg/kg/day) (% aPAD)			
General U.S. Population	0.002 (0.39%)	0.003 (0.61%)	0.002 (0.49%)	0.003 (0.66%)
All Infants (<1 year old)	0.006 (1.17%)	0.008 (1.61%)	0.006 (1.28%)	0.009 (1.71%)
Children 1-2 years old	0.003 (0.58%)	0.004 (0.86%)	0.004 (0.71%)	0.005 (0.93%)
Children 3-5 years old	0.002 (0.48%)	0.004 (0.75%)	0.003 (0.59%)	0.004 (0.80%)
Children 6-12 years old	0.002 (0.35%)	0.003 (0.53%)	0.002 (0.44%)	0.003 (0.58%)
Youth 13-19 years old	0.002 (0.30%)	0.002 (0.44%)	0.002 (0.36%)	0.002 (0.49%)
Adults 20-49 years old	0.002 (0.38%)	0.003 (0.60%)	0.002 (0.47%)	0.003 (0.65%)
Adults 50+ years old	0.002 (0.36%)	0.003 (0.59%)	0.002 (0.47%)	0.003 (0.63%)
Females 13-49 years old	0.002 (0.38%)	0.003 (0.60%)	0.002 (0.48%)	0.003 (0.64%)

For the water monitoring base scenario with central tendency estimates of concentrations and a TAF of 7 or 12, acute dietary exposures to chlorpyrifos (food + water) were estimated to be 0.430 μg/kg/day for both TAF factors at the 99.9th percentile for children 1-2 years old (the most highly exposed subpopulation) and range from 0.225 to 0.226 μg/kg/day for the general population. Expressed as a percent of the aPAD, these exposure estimates range from 11.93% to 11.95% for children 1-2 years old and range from 6.26% to 6.27% for the general U.S. population. For the remaining distributions, acute exposures to chlorpyrifos (food + water) are estimated to range from 0.430 to 0.442 μg/kg/day at the 99.9th percentile for children 1-2 years old (the most highly exposed subpopulation) and from 0.226 to 0.235 μg/kg/day for the general population. Expressed as a percent of the aPAD, these exposure estimates range from 12.0% to 12.3% for children 1-2 years old and range from 6.3% to 6.5% for the general U.S. population. Acute exposures below 100% of the aPAD are reasonably anticipated to result in no harm to exposed populations. This data is presented in Table 7 below.

Table 7. Acute exposures and % of aPAD for dietary exposures (food + water)

Population Subgroup	Base Scenario with Central Tendency Estimates of Concentrations		Upper-Bound Estimates of Concentrations		Central Tendency Estimates with an Extrapolation Past 99.9th Percentile		Upper-Bound Estimates with an Extrapolation Past 99.9th Percentile	
	Exposure (μg/kg/day) (% aPAD)							
	TAF of 7	TAF of 12	TAF of 7	TAF of 12	TAF of 7	TAF of 12	TAF of 7	TAF of 12
General U.S. Population	0.225 (6.26%)	0.226 (6.27%)	0.226 (6.27%)	0.227 (6.32%)	0.226 (6.28%)	0.233 (6.48%)	0.227 (6.29%)	0.235 (6.54%)
All Infants (<1 year old)	0.231 (6.40%)	0.236 (6.56%)	0.237 (6.57%)	0.258 (7.16%)	0.244 (6.78%)	0.259 (7.19%)	0.248 (6.88%)	0.260 (7.23%)
Children 1-2 years old	0.430 (11.93%)	0.430 (11.95%)	0.430 (11.95%)	0.434 (12.06%)	0.432 (12.01%)	0.440 (12.22%)	0.432 (12.01%)	0.442 (12.27%)
Children 3-5 years old	0.311 (8.63%)	0.312 (8.65%)	0.311 (8.65%)	0.314 (8.72%)	0.313 (8.69%)	0.322 (8.95%)	0.313 (8.70%)	0.325 (9.04%)
Children 6-12 years old	0.192 (5.34%)	0.193 (5.36%)	0.193 (5.37%)	0.196 (5.45%)	0.194 (5.40%)	0.201 (5.59%)	0.195 (5.41%)	0.202 (5.61%)
Youth 13-19 years old	0.013 (3.61%)	0.131 (3.63%)	0.131 (3.63%)	0.134 (3.73%)	0.133 (3.69%)	0.139 (3.86%)	0.134 (3.71%)	0.140 (3.90%)
Adults 20-49 years old	0.206 (5.74%)	0.207 (5.75%)	0.207 (5.74%)	0.211 (5.86%)	0.209 (5.82%)	0.22 (6.12%)	0.210 (5.83%)	0.222 (6.17%)

Population Subgroup	Base Scenario with Central Tendency Estimates of Concentrations		Upper-Bound Estimates of Concentrations		Central Tendency Estimates with an Extrapolation Past 99.9th Percentile		Upper-Bound Estimates with an Extrapolation Past 99.9th Percentile	
	Exposure (μg/kg/day) (% aPAD)							
	TAF of 7	TAF of 12	TAF of 7	TAF of 12	TAF of 7	TAF of 12	TAF of 7	TAF of 12
Adults 50+ years old	0.177 (4.91%)	0.177 (4.93%)	0.177 (4.93%)	0.181 (5.04%)	0.180 (5.00%)	0.19 (5.27%)	0.180 (5.00%)	0.191 (5.30%)
Females 13-49 years old	0.146 (4.06%)	0.147 (4.07%)	0.147 (4.08%)	0.153 (4.25%)	0.150 (4.17%)	0.161 (4.47%)	0.151 (4.20%)	0.164 (4.54%)

For the water monitoring base scenario with central tendency estimates of concentrations chronic exposure to chlorpyrifos (water alone) were estimated to be less than 0.001 μg/kg/day for all population groups. Expressed as a percent of the cPAD, these exposure estimates are 0.1% for all population groups. For the water monitoring base scenario with central tendency estimates of concentrations and a TAF of 2.7 or 18, chronic dietary exposure to chlorpyrifos (food + water) were estimated to range from 0.028 to 0.029 for children 1-2 years old (the most highly exposed subpopulation) and from 0.009 to 0.010 μg/kg/day for the general population. Expressed as a percent of the cPAD, these exposure estimates range from 9.3 to 9.8% for children 1-2 years old and from 3.1 to 3.4% for the general U.S. population.

Table 8 presents the chronic exposure estimates for food and drinking water, including the contribution from food handling establishments (FHEs). For the water monitoring base scenario with central tendency estimates of concentrations and a TAF of 2.7 or 18, chronic dietary exposures to chlorpyrifos (food + water + FHE) are estimated to range from 0.038 to 0.039 μg/kg/day for children 1-2 years old (the most highly exposed subpopulation) and from 0.011 to 0.012 μg/kg/day for the general population. Expressed as a percent of the cPAD, these exposure estimates range from 12.7% to 13.2% for children 1-2 years old and from 3.8 to 4.1% for the general U.S. population. Chronic exposures below 100% of the cPAD are reasonably anticipated to result in no harm to exposed populations.

Table 8. **Chronic exposures and % of aPAD using estimates from water monitoring data alone, food + water, and food + water + FHE**

Population Subgroup	Chronic Water Only		Chronic Food + Water				Chronic Food Handling Establishment (FHE) Only		Chronic Food + Water + FHE			
	Dietary Exposure (µg/kg/day)	% cPAD	Dietary Exposure (µg/kg/day)		% cPAD		Dietary Exposure (µg/kg/day)	% cPAD	Dietary Exposure (µg/kg/day)		% cPAD	
			TAF of 2.7	TAF of 18	TAF of 2.7	TAF of 18			TAF of 2.7	TAF of 18	TAF of 2.7	TAF of 18
General U.S. Population	0.000	0.1	0.009	0.010	3.1	3.4	0.002	0.7	0.011	0.012	3.8	4.1
All Infants (<1 year old)	0.000	0.1	0.013	0.016	4.5	5.3	0.004	1.2	0.017	0.020	5.7	6.5
Children 1-2 years old	0.000	0.1	0.028	0.029	9.3	9.8	0.01	3.4	0.038	0.039	12.7	13.2
Children 3-5 years old	0.000	0.1	0.022	0.023	7.2	7.6	0.006	2	0.028	0.029	9.2	9.6
Children 6-12 years old	0.000	0.1	0.013	0.014	4.4	4.7	0.003	1.1	0.016	0.017	5.5	5.8
Youth 13-19 years old	0.000	0.0	0.007	0.008	2.4	2.7	0.002	0.5	0.009	0.010	2.9	3.2
Adults 20-49 years old	0.000	0.1	0.007	0.008	2.5	2.8	0.001	0.5	0.008	0.009	3	3.3
Adults 50+ years old	0.000	0.1	0.008	0.009	2.5	2.9	0.001	0.4	0.009	0.010	2.9	3.3
Females 13-49 years old	0.000	0.1	0.007	0.008	2.3	2.6	0.001	0.5	0.008	0.009	2.8	3.1

Aggregate Risk Assessment

As discussed previously, Dow is not supporting golf courses uses and public health uses including aerial and ground-based fogger treatments to control mosquitoes. However, EPA stated they intended to aggregate these uses with dietary (food + water) exposures. Therefore, even though Dow is not supporting these uses and therefore believes they should not be included in the aggregate assessment, to be comprehensive, individual and aggregate exposure and risk estimates for these uses are presented. The recently updated Residential Standard Operating Procedures (SOPs) (U.S. EPA, 2012) were used to estimate the exposures presented below for post-application scenarios on residential turf from golf course uses and ultra-low volume (ULV) fogger use.

Golf Course Applications – Residential Post-Application Exposure and Risk Assessment

EPA (2011) previously evaluated exposures and risk associated with the golf course use of chlorpyrifos at application rates of 1 lb ai/A and 0.25 lb ai/A for emulsifiable concentrate and granular products. Post-application exposures were reevaluated according to the methods and assumptions obtained from recently updated Residential SOPs (U.S. EPA, 2012) using only the highest application rate of 1 lb ai/A.

Chlorpyrifos from golf course use may lead to potential exposures for adults and children who come into contact with that turf. Turf transferable residues (TTRs) were previously obtained by EPA from studies in California, Indiana, and Mississippi. The TTR values were then adjusted for varying application rates and the resulting TTR value for the 1 lb ai/A application rate was used in this assessment. The short- and intermediate-term dermal toxicity endpoint of 5 mg/kg-bw/day (U.S. EPA, 2011) was used to estimate MOEs for residential golf course post-application exposures.

The MOEs for residential golf course post-application exposures for adults ranged from 524 to 858 for the emulsifiable concentrate, depending on the specific state where the TTR data was obtained. The MOE for the granular product was 726 (only data from California was available for the granular product). The MOEs for residential golf course post-application exposures for Children 11 to 16 ranged from 450 to 736 for the emulsifiable concentrate. The MOE for the granular product was 623 for this age group. The MOEs for residential golf-course post-application exposures for Children 6 to 11 ranged from 383 to 627 for the emulsifiable concentrate. The MOE for the granular product was 531 for this age group. These MOEs are all greater than 100 and therefore indicate that dermal post-application exposures while golfing are not of potential concern. Residential post-application exposures and margins of exposure (MOEs) are estimated for golf courses in the Table 9.

Table 9. Post-application exposures and MOEs for golf course applications

State	Adjusted TTR ($\mu g/cm^2$)	Exposure (mg/kg-bw/day)	MOE
Emulsifiable Concentrate - Adult			
CA	0.031	0.0082	609
IN	0.022	0.0058	858
MS	0.036	0.0095	524
Granular - Adult			
CA	0.026	0.00689	726
Emulsifiable Concentrate - Children (11<16 Years Old)			
CA	0.031	0.0096	522
IN	0.022	0.0068	736
MS	0.036	0.0111	450
Granular Product - Children (11<16 Years Old)			
CA	0.026	0.0080	623
Emulsifiable Concentrate - Children (6<11 Years Old)			
CA	0.031	0.0112	445
IN	0.022	0.0080	627
MS	0.036	0.0131	383
Granular Product - Children (6<11 Years Old)			
CA	0.026	0.0094	531

Ultra-Low Volume (ULV) Aerial and Ground-Based Fogger Applications– Residential Post-Application Exposure and Risk Assessment

EPA (2011) previously evaluated exposures and risks associated with the public health use of chlorpyrifos sprays to control mosquitoes. Ultra-low volume (ULV) aerial (fixed-wing, as per U.S. EPA, 2011) and ground-based fogger applications were evaluated according to the product label, at a maximum application rate of 0.01 lb ai/A. Post-application exposures were reevaluated according to the methods and assumptions obtained from the recently updated Residential SOPs (U.S. EPA, 2012).

Chlorpyrifos from mosquito control applications may settle onto turf, which can lead to potential exposures for adults and children who come into contact with it or accidentally ingest it (children 1-2 years old). Turf transferable residues (TTRs) were calculated assuming that 0.25% and 0.05% of the deposited residue from aerial and ground applications, respectively, are available as dislodgeable residue (U.S. EPA, 2011).

The estimated exposures and MOEs for post-application exposures are shown in Table 10 for dermal exposure and Table 11 for incidental oral exposure. The MOEs for the dermal exposure pathway are above the respective target of 100 for the ground-based treatment at 133 and 264 for children 1-2 and adults, respectively. The MOE for the incidental oral exposure pathway (children 1-2 years old) for the ground-based treatment was also above the respective target of 100 at 130. All MOEs for the aerial applications are below the target MOE of 100. Residential post-application exposures and margins of exposure (MOEs) are estimated for the ULV applications in the Table 11.

Table 10. Post-application dermal exposures and MOEs for ULV applications

Adults		
TTR ($\mu g/cm^2$)	**Exposure (mg/kg-bw/day)**	**MOE**
Aerial Treatment		
2.8×10^{-2}	0.09	53
Ground-Based Treatment		
5.6×10^{-3}	0.02	264
Children 1-2 Years Old		
TTR ($\mu g/cm^2$)	**Exposure (mg/kg-bw/day)**	**MOE**
Aerial Treatment		
2.8×10^{-2}	0.19	27
Ground-Based Treatment		
5.6×10^{-3}	0.04	133

Table 11. Post-application incidental oral exposures and MOEs for ULV applications (children 1-2 years old)

Dermal exposure (mg)	Exposure (mg/kg-bw/day)	MOE
Aerial Treatment		
2.1	0.0038 26	
Ground-Based Treatment		
0.41	0.0008 130	

Residential Post-Application and Dietary Aggregate Exposure Assessment

The final step is producing an aggregate exposure and risk assessment which combines dietary (food + water) and non-dietary exposures (post-application golf course and ULV applications). The results are shown in Table 12. MOEs are above the target of 100 for all golf course treatments and for estimated adult exposure from ground-based ULV treatment. All other MOEs are below the target MOE of 100. Aggregate margins of exposure (MOEs) are estimated in the table below. While some MOEs are less than 100, the MOEs are far higher than EPA would have generated if it proceeded with an aggregate assessment

Table 12. Aggregate MOEs (food + water + post application exposures)

Population Subgroup	MOE			
	Dermal	**Incidental Oral**	**Dietary**	**Total Aggregate**
Post-Application Golf Course Treatments (1.0 lb ai/A)				
Emulsifiable Concentrate				
Adults	524	NA	2,500	433
Granular				
Adults	726	NA	2,500	562
Post-Application Aerial ULV Mosquito Treatments				

Population Subgroup	MOE			
	Dermal	Incidental Oral	Dietary	Total Aggregate
Aerial				
Adults	53	NA	2,500	52
Children 1-2 years	27	26	769	13
Ground				
Adults	264	NA	2,500	239
Children 1-2 years	133	130	769	61

Validation with Biomonitoring Data

Introduction

Reiss (2013) introduced a methodology to compare EPA's food and drinking water modeling estimates with population exposure estimates from biomonitoring data in the NHANES database. NHANES is a national health survey of a sample of the U.S. population conducted by the Centers for Disease Control and Prevention (CDC). In 1999-2002, NHANES included urinary biomonitoring measurements of more than 5000 persons across the U.S. The biomonitoring analysis included measurements of TCP_y, a primary and unique metabolite of chlorpyrifos. From these TCP_y measurements, chlorpyrifos exposures to individuals can be estimated and a distribution of population exposure constructed. Since the aim of the EPA dietary modeling approach is to estimate a distribution of exposures in the population, the back-calculation exposure distribution can be directly compared to the distribution estimated from modeling as a way of validating the modeling estimates.

Methodology

The urinary biomonitoring measurements are collected from a randomized subject of the NHANES study population ages six and older. The samples were collected on a single day for each individual, and are thus indicative of an acute exposure. The available measurements for TCP_y were collected in 1999-2002. More recent data may be available in the future.

The original data included 5277 subjects; however, 849 subjects were excluded due to missing TCP_y, creatinine, body weight, height, or body mass index (BMI), all of which are needed in the exposure back-calculation described below. The final dataset included measurements from 4428 individuals across four years. Detectable TCP_y was reported for 86% of the subjects and the limit of detection of 0.28 μg/l was used to conservatively represent the low exposures to individuals with non-detects.

The steps for estimating chlorpyrifos exposure from the TCP_y excretion data were:

- The daily TCP_y excretion was first adjusted for creatinine. The adjustment process is complicated. It is explained in detail in Reiss (2013) and includes inputs for height, weight and BMI.

- The levels of TCP that are formed directly on food and are thus not the result of chlorpyrifos exposure need to be included. These levels were estimated from a comparison of chlorpyrifos and TCP levels on food. Morgan et al. (2011) found that the average concentration in solid foods were 0.4 ng/g chlorpyrifos and 2.6 ng/g TCP_y, indicating that most TCP_y is actually directly ingested. Since TCP_y is not toxic, its direct ingestion needs to be adjusted for in the back-calculation. The 2.6 ng/g TCP on food would pass through unchanged because TCP is not further metabolized in the body, the 0.4 ng/g chlorpyrifos would be metabolized to 0.16 ng/g TCP, assuming 70% of ingested chlorpyrifos was excreted as TCP_y (Nolan, 1984). The TCP from chlorpyrifos is only 5.7% of the total.

- The amount of TCP excreted is multiplied by 5.7% to get the portion originating from CPF residues. The portion of TCP attributed to chlorpyrifos is multiplied by the molecular weight ratio of CPF to TCP (350.59/198.43), or 10.1%, to estimate the chlorpyrifos exposure.

The steps above yield estimated chlorpyrifos exposures in terms of µg/day. Exposure estimates are more appropriately viewed in terms of mg/kg-bw/day, so conversion of units and division by body weights is necessary. The formula to calculate chlorpyrifos exposure from the daily TCP_y excretion is shown below:

$$\text{Chlorpyrifos exposure (mg/kg/day)} = \text{Daily TCPy excretion } (\mu\text{g/day}) \times \frac{10.1\%}{70\% \times \%\& \times 1000\ \mu\text{'/('}}$$

The equation above was used to estimate single-day chlorpyrifos exposure for each individual.

For the back-calculation, all exposure is assumed to be from chlorpyrifos, although some exposure may be from chlorpyrifos-oxon, which also metabolizes to TCP_y. The amount of TCP_y that comes from chlorpyrifos versus chlorpyrifos-oxon is unknown. However, the molecular weights of chlorpyrifos and chlorpyrifos-oxon are similar; thus, the estimate is not significantly affected by assuming that all TCP_y derived from chlorpyrifos.

There is one additional step needed to create a population distribution. NHANES contains weighting factors for each subject that represents the relative coverage of each subject's characteristics (age, gender, etc.). Subjects with characteristics that are underrepresented in the survey are given higher weighting than those that are overrepresented. The weighted distribution is summarized in Table 13.

Table 13. Estimated chlorpyrifos exposures (mg/kg-bw/day) reported at select percentiles for several subpopulations based on NHANES data

Subpopulation	Un-weighted Sample Size	Percentiles					
		50^{th}	70^{th}	90^{th}	95^{th}	99^{th}	99.9^{th}
Children 6-12 yr	1,227	9.1×10^{-6}	1.5×10^{-5}	2.9×10^{-5}	4.5×10^{-5}	1.3×10^{-4}	2.9×10^{-4}
Youth 13-19 yr	1,295	5.1×10^{-6}	7.9×10^{-6}	1.8×10^{-5}	2.5×10^{-5}	6.8×10^{-5}	1.4×10^{-4}
Adults 20-49 yr	1,519	3.8×10^{-6}	6.5×10^{-6}	1.3×10^{-5}	1.8×10^{-5}	4.5×10^{-5}	1.8×10^{-4}
Adults 50+ yr	387	3.4×10^{-6}	5.7×10^{-6}	1.4×10^{-5}	2.1×10^{-5}	4.2×10^{-5}	7.5×10^{-5}
Females 13-49 yr	1,497	3.6×10^{-6}	6.3×10^{-6}	1.3×10^{-5}	1.8×10^{-5}	4.3×10^{-5}	1.2×10^{-4}

Comparison of EPA Exposure Estimates with Biomonitoring Exposure Estimates

Acute Exposure Estimates

EPA uses the 99.9^{th} percentile of the population distribution for acute risk assessment. From EPA's food-only exposure estimates in the 2011 preliminary risk assessment, the agreement between the TCP_y-based estimates and EPA's estimates is remarkable, as shown in Figure 6. Comparisons were made for five of the subpopulations used in the EPA modeling. Since the minimum age in NHANES is 6 years, comparisons cannot be made for the younger subpopulations. The TCP_y-derived estimates are within a factor of three of the EPA food-only exposure estimates and most are even closer.

In contrast to the close agreement between the TCP_y-derived estimates and the food-only dietary modeling estimates when drinking water is added to the food-only estimates, the agreement at the 99.9^{th} percentile is very poor. Figure 7 shows a comparison of the TCP_y-derived 99.9^{th} percentile estimates and the food-only plus drinking water estimates for grapes (EPA's higher-end scenario), including the drinking water estimates for typical and maximum application rates.

Figure 6. Comparison of TCP_y-derived 99.9th percentile chlorpyrifos exposures to food-only 99.9th percentile chlorpyrifos exposures estimated by EPA with dietary exposure model in 2011 risk assessment

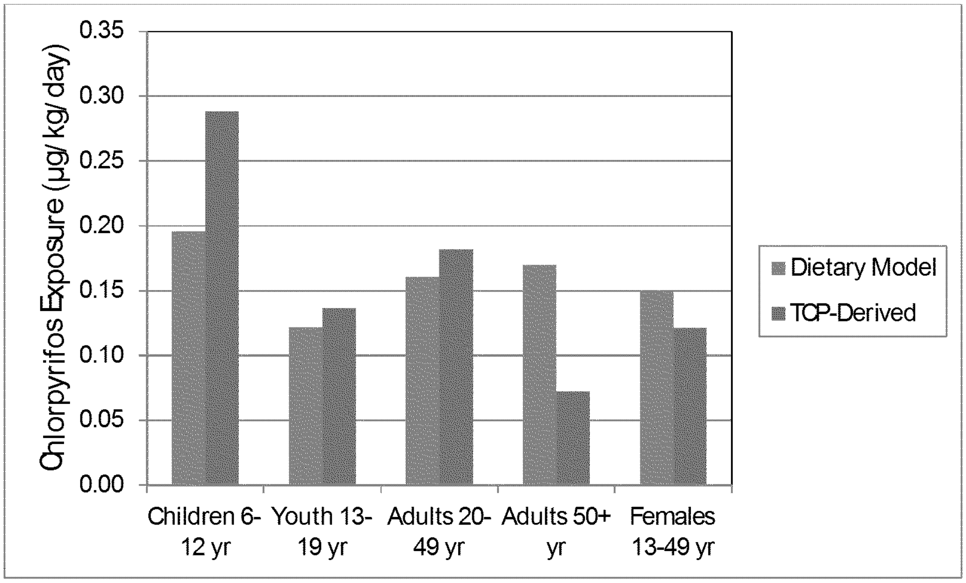
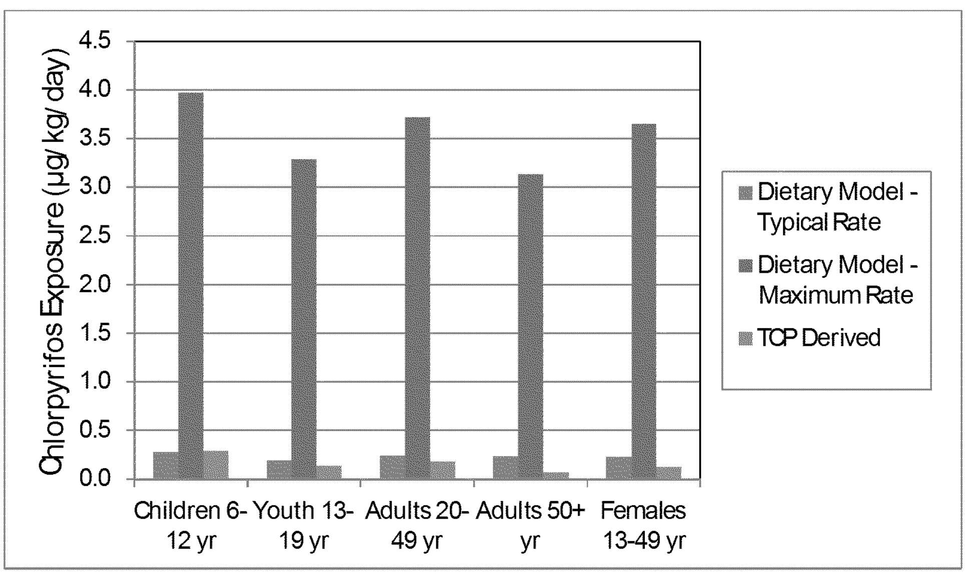


Figure 7. Comparison of TCP_y-derived 99.9th percentile chlorpyrifos exposures to food plus drinking water 99.9th percentile chlorpyrifos exposures for grapes estimated by EPA with dietary and drinking water exposure models in 2011 risk assessment



The estimates from the exposure model using the typical rates are similar to the TCP_y-derived estimates. However, using the maximum rate scenario for the drinking water estimates, the EPA modeling estimates exceed the TCP_y-derived estimates by a factor of 14 to 43-fold.

These comparisons generally show that there is good agreement between the dietary exposure models for food-only and the estimates derived from the NHANES biomonitoring data. When using typical application rates to derive the drinking water estimates, the food plus drinking water estimates were similar to the biomonitoring estimates. However, when using the maximum application rates alone without considering the other overall conservative factors of the theoretical watershed used in the EPA modeling, the food plus drinking water estimates substantially exceed the biomonitoring.

Therefore, these comparisons show that the high-end drinking water scenarios used by EPA, particularly when using the maximum application rate, greatly exceed the exposure seen in the population from real-world biomonitoring data. While it is possible that there are very small groups of people that may experience these higher drinking water exposures than captured by NHANES, it is not apparent from a large dataset of chlorpyrifos-metabolite data across the population.

Chronic Exposures

The mean exposure values from DEEM-FCID are used for chronic risk assessment. For EPA's food-only exposure estimates, the agreement between the TCP_y-derived and EPA dietary estimates is also remarkable as shown in Figure 8. This agreement is despite the uncertainty associated with comparing a chronic dietary modeling estimate with the single day measurement of TCP_y from NHANES. As with the acute section, comparisons were made for five of the subpopulations used in the EPA modeling. Since the minimum age in NHANES is 6 years, comparisons cannot be made for the younger subpopulations. The TCP_y-derived estimates are within 25% of the EPA dietary exposure estimates.

In contrast to the close agreement between the TCP_y-derived estimates and the food-only dietary modeling estimates, when drinking water is added to the food-only estimates, the agreement is poor. Figure 9 shows a comparison of the mean TCP_y-derived estimates and the food-only plus drinking water estimates for grapes (EPA's higher-end scenario), including the drinking water estimates for typical and maximum application rates.

Figure 8. Comparison of TCP_y-derived mean chlorpyrifos exposures to food-only mean chlorpyrifos exposures estimated by EPA with dietary exposure model in the 2011 risk assessment

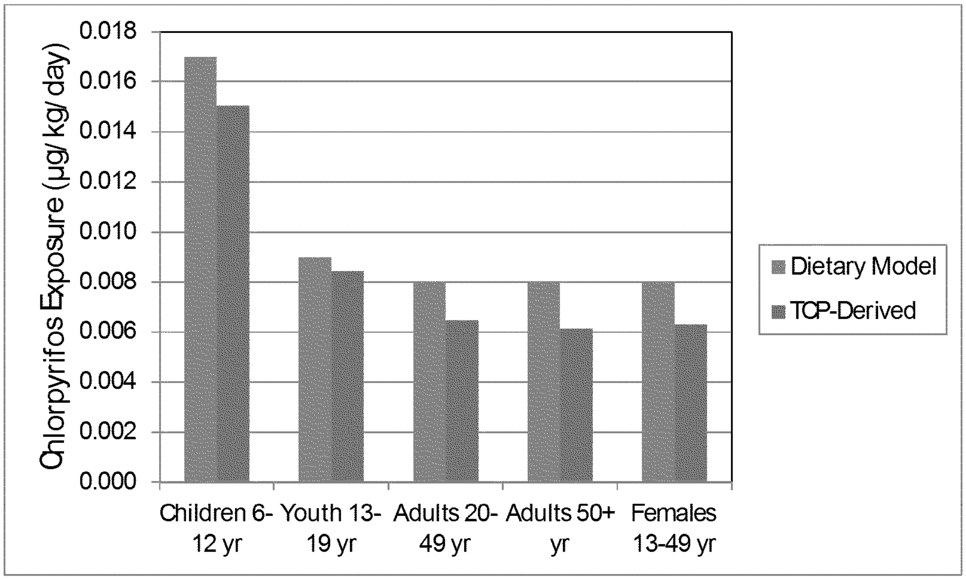
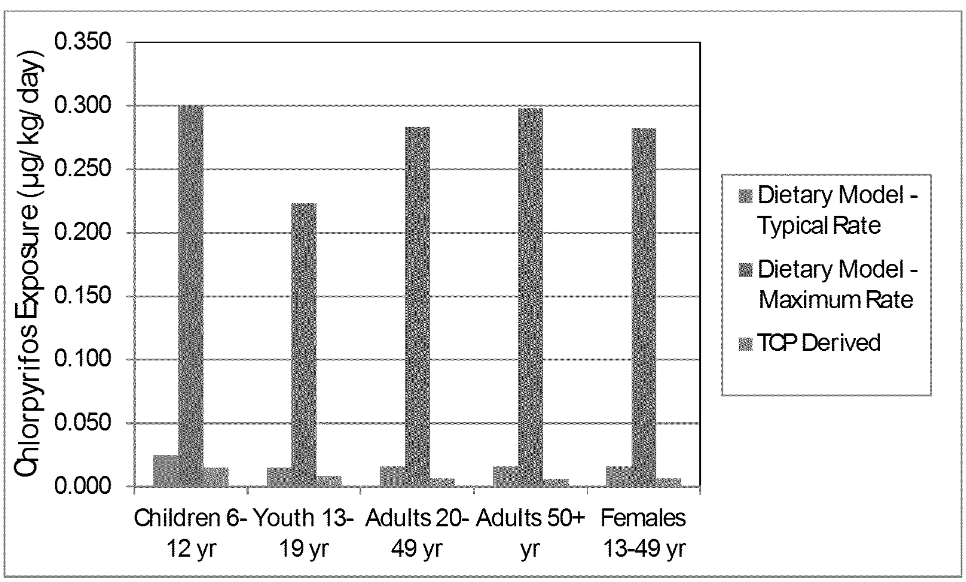


Figure 9. Comparison of TCP_y-derived mean chlorpyrifos exposures to food plus drinking water mean chlorpyrifos exposures for grapes estimated by EPA with dietary and drinking water exposure models in the 2011 risk assessment



The estimates from the exposure model using the typical rates all exceed the TCP_y-derived estimates. Using the maximum rate scenario for the drinking water estimates, the EPA modeling estimates exceed the TCP_y-derived estimates by a factor of 20 to 49-fold.

As with the acute comparisons, these comparisons generally show that there is a good agreement between the dietary exposure models for food-only and the estimates derived from the NHANES biomonitoring data using the mean exposures, the standard value for chronic dietary and drinking water risk assessment. The food plus EPA drinking water estimates substantially exceed the biomonitoring estimates, by as much as a factor of 48-fold.

Therefore, these comparisons show that the high-end drinking water scenarios used by EPA, particularly when using the maximum application rate, greatly exceed the mean exposure seen in the population from real-world data. While it is possible that there are small groups of people that may experience higher drinking water exposures than captured by NHANES, it is not apparent from a large dataset of chlorpyrifos-metabolite data across the population.

Comparison of Refined Exposure Estimates with Biomonitoring Exposure Estimates

Figures 10 and 11 show a comparison of the TCP_y-derived exposure estimates and the food plus water DEEM-FCID estimates using an estimate of the drinking water distribution from monitoring data. The drinking water distribution with the central tendency estimates from Mosquin et al. (2011) was used for this analysis, although the results are similar for all of the distributions that were developed. Figure 10 shows the results for acute exposure and Figure 11 shows the results for chronic exposures.

The food plus water exposure estimates are very similar to the food only estimates from the 2011 risk assessment, as water is a small contributor to the refined estimates. The updated version of DEEM-FCID also results in smaller water exposure estimates. The agreement between TCP_y-derived and DEEM-FCID food plus water exposure estimates is excellent. All of the TCP_y-derived and DEEM-FCID estimates are within about 20% of another.

This analysis should give confidence to EPA in the use of the extensive water monitoring to represent drinking water exposure.

Figure 10. Comparison of TCP_y-derived chlorpyrifos 99.9th percentile exposures to food plus drinking water 99.9th percentile chlorpyrifos exposures estimated using refined methods, including drinking water monitoring data

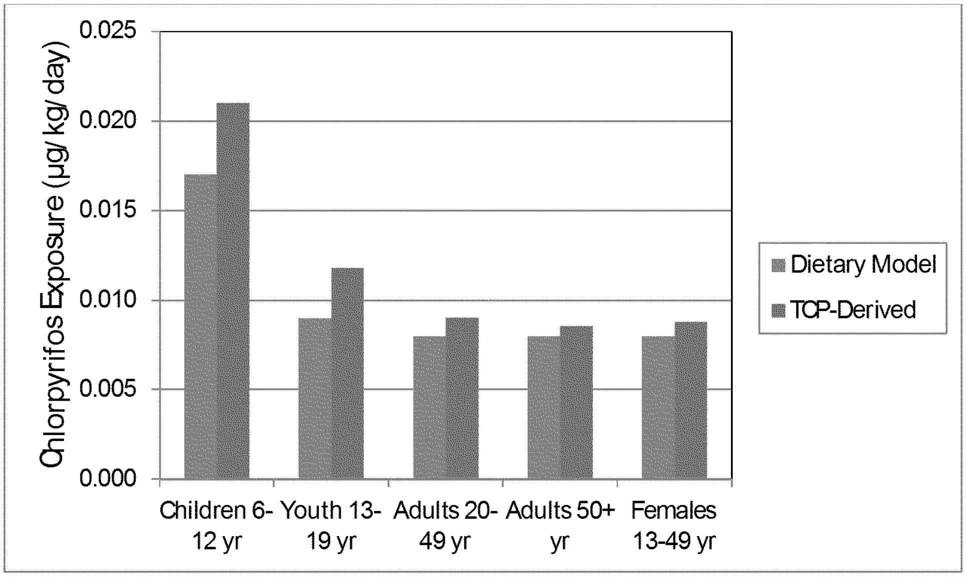
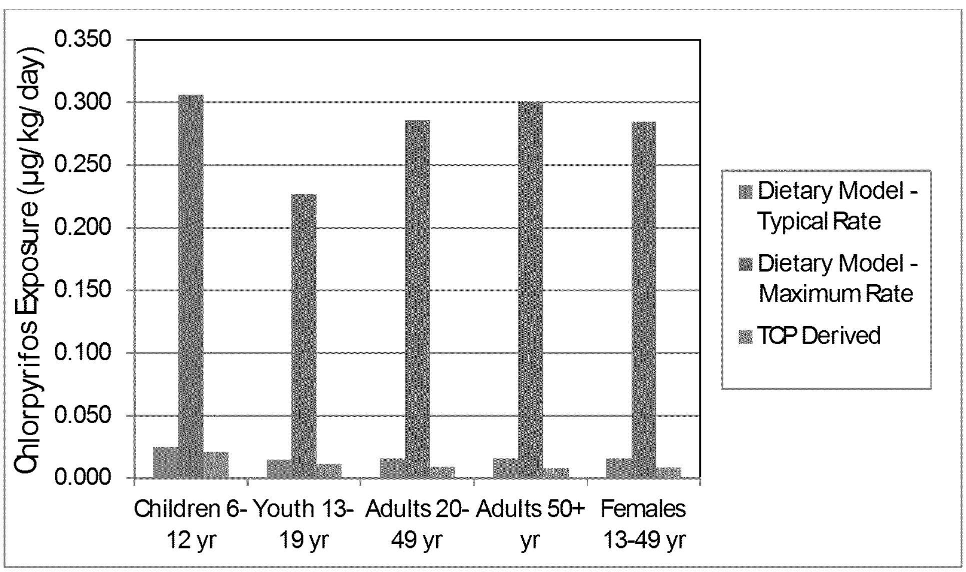


Figure 11. Comparison of TCP_y-derived chlorpyrifos mean exposures to food plus drinking water mean chlorpyrifos exposures estimated using refined methods, including drinking water monitoring data



Discussion of Uncertainties

As with any risk assessment, this one has some uncertainties. The major difference between the current assessment and the EPA 2011 preliminary assessment is the use of drinking water monitoring data instead of modeling calculations. As was described above, the EPA modeling calculations are highly uncertain and have been shown to substantially overestimate concentrations for virtually all pesticides. Nonetheless, there is also uncertainty in the monitoring concentrations.

Peak pesticide concentrations can be driven by events that combine unusual circumstances such as small watersheds, high use of a single pesticide in a watershed, soils vulnerable to runoff, and other possible factors. Even extensive monitoring networks cannot measure every occurrence of a large concentration. However, with over 30,000 samples in the last several decades, the NAWQA and NASQAN programs provide extensive information about chlorpyrifos and chlorpyrifos-oxon concentrations in the environment. Further, the analysis in this report includes the NAWQA and NASQAN data collected before the residential phase-out of chlorpyrifos, which represents a potential overestimation of concentrations. That even the peak concentration over more than 30,000 samples does not approach the modeling estimates from EPA shows that there are substantial uncertainties with the modeling estimates. Even most of EPA's annual average concentration modeling estimates are higher than the peak concentration in the NAWQA and NASQAN datasets.

There is also uncertainty in the TCP_y back-calculation. While chlorpyrifos is quickly excreted from the body, urinary TCP_y levels have been shown to declines more slowly, with a half-life of >24 hr (Nolan, 1984). As a result, TCP_y levels should give a reasonable estimate of acute or steady-state oral exposures, but may vary 2-fold based on ingestion time vs. sampling. Also, substantial portions of TCP_y form directly on food items; thus, most TCP_y exposure is the result of direct ingestion. This was accounted for in the back-calculation by assuming that only 14.1% of ingested TCP_y came from chlorpyrifos. However, there is variability around this percentage and only a mean value could be assumed for each subject in the NHANES survey. The back-calculation is strengthened by the large sample size of >4,000 subjects.

Conclusions

This report provides an aggregate risk assessment for chlorpyrifos that has been refined compared to the preliminary risk assessment conducted by EPA in 2011. EPA's 2011 risk assessment found high risks for drinking water exposures, while food only exposures did not exceed levels of concern. The principal difference in the refined risk assessment is the use of water monitoring data instead of water modeling estimates to define the drinking water concentration distribution in the risk assessment.

Across more than 30,000 samples, the highest chlorpyrifos surface water measurement was 0.57 ppb in the USGS NAWQA program. Mosquin (2014) applied survey statistical methodologies to estimate the upper percentile concentrations of the NAWQA and NASQAN datasets. This distribution was used in the DEEM-FCID dietary exposure model along with food residue and consumption data to estimate dietary exposures. In the refined assessment, the drinking water exposures were substantially lower than in EPA's estimates and were about $1/10^{th}$ of the food exposures. The combined food and drinking water exposure is well below EPA's aPAD and cPAD for chlorpyrifos, indicating minimal risk.

The exposure estimates in this report were validated using urinary biomonitoring measurements of TCP_y, a principal metabolite of chlorpyrifos. The EPA 2011 exposure estimates vastly exceeded the population exposure estimates made from the TCP_y data. However, the refined assessment presented in this report agrees well with the biomonitoring data. This strongly shows that the estimates presented in this report are an improvement beyond those presented in the EPA 2011a,b reports.

An aggregate assessment was also performed, including golf course and ULV mosquito uses. Dow is not supporting these uses, but they were included for completeness because EPA says it intends to include them in the revised risk assessment. When the golf courses uses were included, the aggregate assessment had MOEs less than 100. For the mosquito uses, the MOEs were less than 100, except for adult ground application use.

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Appendix 1: Representative Input and Output Files for the Acute and Chronic Dietary Assessments

```
US EPA                                                      Ver. 3.18, 03-08-d
DEEM-FCID Acute analysis for CHLORPYRIFOS-ACUTE
Residue file name: J:\1305765.000 (Dow Chlorpyrifos Aggregate Risk
Assessment)\Residue Files\Residue Files with NAWQA Inputs
(final)\ACUTE_NOH20FIXFOOD7JUNVC36POD (CONVERTED) -  QAd by KDT -- CPFW -- TAF is
7.R08
Analysis Date 04-29-2014             Residue file dated: 04-29-2014/12:49:54
Reference dose (aRfD) = 0.0036 mg/kg bw/day
Comment: Food + Water (CPFW; TAF is 7); CFOS POD of 0.0036 Used
----------------------------------------------------------------------------------
RDL indices and parameters for Monte Carlo Analysis:
Index Dist Parameter #1           Param #2    Param #3    Comment
  #   Code
----- ---- ------------           ----------- ----------- ----------
  1    6   asparagus2008-9.rdf
  2    6   Cranberry06.rdf
  3    6   Apple2009.rdf
  4    6   Almonds PDP 2007.RDF
  5    6   Green_beans_fresh.rdf
  6    6   Grapes2009.rdf
  7    6   Bananas.rdf
  8    6   Strawberry2008rdf.rdf
  9    6   Broccoli2006.rdf
  10   6   BrusselssproutsfBroc2006.rdf
  11   6   CabbagefBorc2006.rdf
  12   6   Cauliflower.rdf
  13   6   kiwi.rdf
  14   6   Cherry2007.rdf
  15   6   Cucumbers2009.rdf
  16   6   PeachCanned.RDF
  17   6   Grapefruit.rdf
  18   6   Lemon.rdf
  19   6   Oranges.rdf
  20   6   OrangeJuice2004.rdf
  21   6   Peach2008.rdf
  22   6   Sweets2003to2008.rdf
  23   6   SweetPeppers2002.rdf
  24   6   Asparagus_canned.rdf
  25   6   kale2006-8.rdf
  26   6   Plums2005.rdf
  27   6   onions2002-3.rdf
  28   6   Collards2006-8.rdf
  29   6   Sweets2003to200865.rdf
  30   6   PorkAdipose.rdf
  31   6   Pears2003.rdf
  34   6   Nectarines2008.rdf
  35   6   Tangerine.RDF
  38   6   Green_beans_canned.rdf
  40   6   CITRUS 100.RDF
  42   6   Wheat grain 2005.RDF
  43   6   Grapejuicerdf2008.rdf
  45   6   Graperaisins2007rdf.rdf
  46   6   Sweetcorn.rdf
  50   6   Prunes.rdf
  51   6   PEAS.RDF
  52   6   Lemon Juice.RDF
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  53   6   Lime Juice.RDF
  54   6   Tangerine Juice.RDF
  55   6   Filbertfalmond.RDF
  56   6   Pecanfalmond.RDF
  57   6   Walnutfalmond.RDF
  58   6   CPFW -- Acute -- Water-only.rdf

  EPA      Crop Food Name                        Def Res     Adj.Factors  RDL
Comment
  Code      Grp                                   (ppm)       #1     #2   Pntr
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1400003000 14   Almond                            1.000000   1.000  1.000   4
1400003001 14   Almond-babyfood                   1.000000   1.000  1.000   4
1400004000 14   Almond, oil                       1.000000   2.000  1.000   4
1400004001 14   Almond, oil-babyfood              1.000000   2.000  1.000   4
1100007000 11   Apple, fruit with peel            1.000000   1.000  1.000   3
1100008000 11   Apple, peeled fruit               1.000000   0.150  1.000   3
1100008001 11   Apple, peeled fruit-babyfood      1.000000   0.150  1.000   3
1100009000 11   Apple, dried                      1.000000   1.200  1.000   3
1100009001 11   Apple, dried-babyfood             1.000000   1.200  1.000   3
1100010000 11   Apple, juice                      0.000850   0.150  1.000
1100010001 11   Apple, juice-babyfood             0.000850   0.150  1.000
1100011000 11   Apple, sauce                      0.000650   0.150  1.000
1100011001 11   Apple, sauce-babyfood             0.000650   0.150  1.000
9500019000 O    Asparagus
                   110-Uncooked; Fresh or N/S; Cook Meth N/S
                                                  1.000000   1.000  1.000   1
                   212-Cooked; Fresh or N/S; Boiled
                                                  1.000000   0.940  1.000   1
                   213-Cooked; Fresh or N/S; Fried
                                                  1.000000   0.940  1.000   1
                   222-Cooked; Frozen; Boiled     1.000000   0.940  1.000   1
                   242-Cooked; Canned; Boiled     1.000000   0.940  1.000  24
9500023000 O    Banana                            1.000000   1.000  1.000   7
9500023001 O    Banana-babyfood                   1.000000   1.000  1.000   7
9500024000 O    Banana, dried                     0.002000   3.900  1.000
9500024001 O    Banana, dried-babyfood            0.002000   3.900  1.000   7
0603030000 6C   Bean, black, seed
                   210-Cooked; Fresh or N/S; Cook Meth N/S
                                                  0.000630   1.000  1.000
                   230-Cooked; Dried; Cook Meth N/S
                                                  0.000630   1.000  1.000
                   232-Cooked; Dried; Boiled      0.000630   1.000  1.000
0602031000 6B   Bean, broad, succulent            1.000000   0.580  1.000  51
0603032000 6C   Bean, broad, seed
                   210-Cooked; Fresh or N/S; Cook Meth N/S
                                                  0.000630   1.000  1.000
                   230-Cooked; Dried; Cook Meth N/S
                                                  0.000630   1.000  1.000
                   232-Cooked; Dried; Boiled      0.000630   1.000  1.000
0602033000 6B   Bean, cowpea, succulent           1.000000   0.580  1.000  51
0603034000 6C   Bean, cowpea, seed
                   232-Cooked; Dried; Boiled      0.000630   1.000  1.000
0603035000 6C   Bean,  great northern, seed
                   210-Cooked; Fresh or N/S; Cook Meth N/S
                                                  0.000630   1.000  1.000
                   212-Cooked; Fresh or N/S; Boiled
                                                  0.000630   1.000  1.000
                   230-Cooked; Dried; Cook Meth N/S
                                                  0.000630   1.000  1.000
                   232-Cooked; Dried; Boiled      0.000630   1.000  1.000
                   242-Cooked; Canned; Boiled     0.000630   1.000  1.000
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0603036000	6C	Bean, kidney, seed				
		210-Cooked; Fresh or N/S; Cook Meth N/S	0.000630	1.000	1.000	
		211-Cooked; Fresh or N/S; Baked	0.000630	1.000	1.000	
		212-Cooked; Fresh or N/S; Boiled	0.000630	1.000	1.000	
		221-Cooked; Frozen; Baked	0.000630	1.000	1.000	
		232-Cooked; Dried; Boiled	0.000630	1.000	1.000	
		240-Cooked; Canned; Cook Meth N/S	0.000630	1.000	1.000	
		242-Cooked; Canned; Boiled	0.000630	1.000	1.000	
0602037000	6B	Bean, lima, succulent	1.000000	0.580	1.000	51
0603038000	6C	Bean, lima, seed				
		110-Uncooked; Fresh or N/S; Cook Meth N/S	0.000630	1.000	1.000	
		210-Cooked; Fresh or N/S; Cook Meth N/S	0.000630	1.000	1.000	
		222-Cooked; Frozen; Boiled	0.000630	1.000	1.000	
		230-Cooked; Dried; Cook Meth N/S	0.000630	1.000	1.000	
		232-Cooked; Dried; Boiled	0.000630	1.000	1.000	
0603039000	6C	Bean, mung, seed				
		110-Uncooked; Fresh or N/S; Cook Meth N/S	0.000630	1.000	1.000	
		210-Cooked; Fresh or N/S; Cook Meth N/S	0.000630	1.000	1.000	
		212-Cooked; Fresh or N/S; Boiled	0.000630	1.000	1.000	
		213-Cooked; Fresh or N/S; Fried	0.000630	1.000	1.000	
		221-Cooked; Frozen; Baked	0.000630	1.000	1.000	
		232-Cooked; Dried; Boiled	0.000630	1.000	1.000	
		233-Cooked; Dried; Fried	0.000630	1.000	1.000	
0603040000	6C	Bean, navy, seed				
		210-Cooked; Fresh or N/S; Cook Meth N/S	0.000630	1.000	1.000	
		212-Cooked; Fresh or N/S; Boiled	0.000630	1.000	1.000	
		230-Cooked; Dried; Cook Meth N/S	0.000630	1.000	1.000	
		232-Cooked; Dried; Boiled	0.000630	1.000	1.000	
		242-Cooked; Canned; Boiled	0.000630	1.000	1.000	
0603041000	6C	Bean, pink, seed				
		212-Cooked; Fresh or N/S; Boiled	0.000630	1.000	1.000	
		232-Cooked; Dried; Boiled	0.000630	1.000	1.000	
0603042000	6C	Bean, pinto, seed				
		210-Cooked; Fresh or N/S; Cook Meth N/S	0.000630	1.000	1.000	
		211-Cooked; Fresh or N/S; Baked	0.000630	1.000	1.000	
		212-Cooked; Fresh or N/S; Boiled	0.000630	1.000	1.000	
		213-Cooked; Fresh or N/S; Fried	0.000630	1.000	1.000	
		221-Cooked; Frozen; Baked	0.000630	1.000	1.000	
		230-Cooked; Dried; Cook Meth N/S	0.000630	1.000	1.000	
		232-Cooked; Dried; Boiled	0.000630	1.000	1.000	
0601043000	6A	Bean, snap, succulent				
		110-Uncooked; Fresh or N/S; Cook Meth N/S	1.000000	0.580	1.000	5

		210-Cooked; Fresh or N/S; Cook Meth N/S	1.000000	0.580	1.000	5
		211-Cooked; Fresh or N/S; Baked	1.000000	0.580	1.000	5
		212-Cooked; Fresh or N/S; Boiled	1.000000	0.580	1.000	5
		213-Cooked; Fresh or N/S; Fried	1.000000	0.580	1.000	5
		215-Cooked; Fresh or N/S; Boiled/baked	1.000000	0.580	1.000	5
		220-Cooked; Frozen; Cook Meth N/S	1.000000	0.580	1.000	5
		221-Cooked; Frozen; Baked	1.000000	0.580	1.000	5
		222-Cooked; Frozen; Boiled	1.000000	0.580	1.000	5
		232-Cooked; Dried; Boiled	1.000000	0.580	1.000	5
		240-Cooked; Canned; Cook Meth N/S	1.000000	0.580	1.000	38
		242-Cooked; Canned; Boiled	1.000000	0.580	1.000	38
0601043001	6A	Bean, snap, succulent-babyfood	1.000000	0.580	1.000	5
3100044000	31	Beef, meat	0.000500	0.500	1.000	
3100044001	31	Beef, meat-babyfood	0.000500	0.500	1.000	
3100045000	31	Beef, meat, dried	0.000500	1.920	1.000	
3100046000	31	Beef, meat byproducts	0.000500	0.500	1.000	
3100046001	31	Beef, meat byproducts-babyfood	0.000500	0.500	1.000	
3100047000	31	Beef, fat	0.000500	0.500	1.000	
3100047001	31	Beef, fat-babyfood	0.000500	0.500	1.000	
3100048000	31	Beef, kidney	0.000500	0.500	1.000	
3100049000	31	Beef, liver	0.000500	0.500	1.000	
3100049001	31	Beef, liver-babyfood	0.000500	0.500	1.000	
0101052000	1A	Beet, sugar	0.002000	1.000	1.000	
0101052001	1A	Beet, sugar-babyfood	0.002000	1.000	1.000	
0101053000	1A	Beet, sugar, molasses	0.002000	1.000	1.000	
0101053001	1A	Beet, sugar, molasses-babyfood	0.002000	1.000	1.000	
0501061000	5A	Broccoli				
		110-Uncooked; Fresh or N/S; Cook Meth N/S	1.000000	1.000	1.000	9
		210-Cooked; Fresh or N/S; Cook Meth N/S	1.000000	0.940	1.000	9
		211-Cooked; Fresh or N/S; Baked	1.000000	0.940	1.000	9
		212-Cooked; Fresh or N/S; Boiled	1.000000	0.940	1.000	9
		213-Cooked; Fresh or N/S; Fried	1.000000	0.940	1.000	9
		220-Cooked; Frozen; Cook Meth N/S	1.000000	0.940	1.000	9
		221-Cooked; Frozen; Baked	1.000000	0.940	1.000	9
		222-Cooked; Frozen; Boiled	1.000000	0.940	1.000	9
		232-Cooked; Dried; Boiled	1.000000	0.940	1.000	9
		242-Cooked; Canned; Boiled	1.000000	0.940	1.000	9
0501061001	5A	Broccoli-babyfood	1.000000	0.940	1.000	9
0501062000	5A	Broccoli, Chinese	1.000000	0.940	1.000	9
0502063000	5B	Broccoli raab	1.000000	0.830	1.000	25
0501064000	5A	Brussels sprouts				
		110-Uncooked; Fresh or N/S; Cook Meth N/S	1.000000	1.000	1.000	10
		212-Cooked; Fresh or N/S; Boiled	1.000000	0.940	1.000	10
		222-Cooked; Frozen; Boiled	1.000000	0.940	1.000	10
0501069000	5A	Cabbage				
		110-Uncooked; Fresh or N/S; Cook Meth N/S	1.000000	1.000	1.000	11
		150-Uncooked; Cured etc; Cook Meth N/S				

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                                            1.000000   1.000  1.000  11
                  210-Cooked; Fresh or N/S; Cook Meth N/S
                                            1.000000   0.830  1.000  11
                  211-Cooked; Fresh or N/S; Baked
                                            1.000000   0.830  1.000  11
                  212-Cooked; Fresh or N/S; Boiled
                                            1.000000   0.830  1.000  11
                  213-Cooked; Fresh or N/S; Fried
                                            1.000000   0.830  1.000  11
                  221-Cooked; Frozen; Baked      1.000000   0.830  1.000  11
                  230-Cooked; Dried; Cook Meth N/S
                                            1.000000   0.830  1.000  11
                  232-Cooked; Dried; Boiled      1.000000   0.830  1.000  11
                  240-Cooked; Canned; Cook Meth N/S
                                            1.000000   0.830  1.000  11
                  242-Cooked; Canned; Boiled     1.000000   0.830  1.000  11
                  245-Cooked; Canned; Boiled/baked
                                            1.000000   0.830  1.000  11
                  250-Cooked; Cured etc; Cook Meth N/S
                                            1.000000   0.830  1.000  11
                  255-Cooked; Cured etc; Boiled/baked
                                            1.000000   0.830  1.000  11
0502070000 5B   Cabbage, Chinese, bok choy
                  110-Uncooked; Fresh or N/S; Cook Meth N/S
                                            1.000000   1.000  1.000  25
                  150-Uncooked; Cured etc; Cook Meth N/S
                                            1.000000   1.000  1.000  25
                  210-Cooked; Fresh or N/S; Cook Meth N/S
                                            1.000000   0.830  1.000  25
                  213-Cooked; Fresh or N/S; Fried
                                            1.000000   0.830  1.000  25
                  221-Cooked; Frozen; Baked      1.000000   0.830  1.000  25
0501071000 5A   Cabbage, Chinese, napa          1.000000   0.830  1.000  10
0501072000 5A   Cabbage, Chinese, mustard       1.000000   0.830  1.000  10
0501083000 5A   Cauliflower
                  110-Uncooked; Fresh or N/S; Cook Meth N/S
                                            1.000000   1.000  1.000  12
                  150-Uncooked; Cured etc; Cook Meth N/S
                                            1.000000   1.000  1.000  12
                  210-Cooked; Fresh or N/S; Cook Meth N/S
                                            1.000000   0.940  1.000  12
                  211-Cooked; Fresh or N/S; Baked
                                            1.000000   0.940  1.000  12
                  212-Cooked; Fresh or N/S; Boiled
                                            1.000000   0.940  1.000  12
                  213-Cooked; Fresh or N/S; Fried
                                            1.000000   0.940  1.000  12
                  221-Cooked; Frozen; Baked      1.000000   0.940  1.000  12
                  222-Cooked; Frozen; Boiled     1.000000   0.940  1.000  12
                  242-Cooked; Canned; Boiled     1.000000   0.940  1.000  12
                  250-Cooked; Cured etc; Cook Meth N/S
                                            1.000000   0.940  1.000  12
1201090000 12A  Cherry
                  110-Uncooked; Fresh or N/S; Cook Meth N/S
                                            1.000000   1.000  1.000  14
                  120-Uncooked; Frozen; Cook Meth N/S
                                            1.000000   1.000  1.000  14
                  210-Cooked; Fresh or N/S; Cook Meth N/S
                                            1.000000   1.160  1.000  14
                  211-Cooked; Fresh or N/S; Baked
                                            1.000000   1.160  1.000  14
                  213-Cooked; Fresh or N/S; Fried
                                            1.000000   1.160  1.000  14
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		223-Cooked; Frozen; Fried	1.000000	1.160	1.000	14
		240-Cooked; Canned; Cook Meth N/S	1.000000	0.590	1.000	14
		241-Cooked; Canned; Baked	1.000000	0.590	1.000	14
1201090001	12A	Cherry-babyfood	1.000000	0.590	1.000	14
1201091000	12A	Cherry, juice	1.000000	0.300	1.000	14
1201091001	12A	Cherry, juice-babyfood	1.000000	0.300	1.000	14
4000093000	40	Chicken, meat	0.000750	0.500	1.000	
4000093001	40	Chicken, meat-babyfood	0.000750	0.500	1.000	
4000094000	40	Chicken, liver	0.004900	0.500	1.000	
4000095000	40	Chicken, meat byproducts	0.004900	0.500	1.000	
4000095001	40	Chicken, meat byproducts-babyfoo	0.004900	0.500	1.000	
4000096000	40	Chicken, fat	0.004900	0.500	1.000	
4000096001	40	Chicken, fat-babyfood	0.004900	0.500	1.000	
4000097000	40	Chicken, skin	0.004900	0.500	1.000	
4000097001	40	Chicken, skin-babyfood	0.004900	0.500	1.000	
0603098000	6C	Chickpea, seed				
		110-Uncooked; Fresh or N/S; Cook Meth N/S	0.000630	1.000	1.000	
		210-Cooked; Fresh or N/S; Cook Meth N/S	0.000630	1.000	1.000	
		212-Cooked; Fresh or N/S; Boiled	0.000630	1.000	1.000	
		232-Cooked; Dried; Boiled	0.000630	1.000	1.000	
		234-Cooked; Dried; Fried/baked	0.000630	1.000	1.000	
0603098001	6C	Chickpea, seed-babyfood	0.000630	1.000	1.000	
0603099000	6C	Chickpea, flour	0.000630	1.000	1.000	
1001106000	10A	Citron	1.000000	1.000	1.000	40
1001107000	10A	Citrus hybrids	1.000000	1.000	1.000	40
1001108000	10A	Citrus, oil	0.002800	1.000	1.000	
0502117000	5B	Collards	1.000000	0.830	1.000	28
1500120000	15	Corn, field, flour	0.001110	0.220	1.000	
1500120001	15	Corn, field, flour-babyfood	0.001110	0.220	1.000	
1500121000	15	Corn, field, meal	0.001110	0.220	1.000	
1500121001	15	Corn, field, meal-babyfood	0.001110	0.220	1.000	
1500122000	15	Corn, field, bran	0.001110	0.220	1.000	
1500123000	15	Corn, field, starch	0.001110	0.220	1.000	
1500123001	15	Corn, field, starch-babyfood	0.001110	0.220	1.000	
1500124000	15	Corn, field, syrup	0.001110	0.050	1.000	
1500124001	15	Corn, field, syrup-babyfood	0.001110	0.050	1.000	
1500125000	15	Corn, field, oil	0.001110	4.500	1.000	
1500125001	15	Corn, field, oil-babyfood	0.001110	4.500	1.000	
1500127000	15	Corn, sweet	0.001100	0.940	1.000	46
1500127001	15	Corn, sweet-babyfood	0.001100	0.940	1.000	46
2003128000	20C	Cottonseed, oil	0.003000	0.375	1.000	
2003128001	20C	Cottonseed, oil-babyfood	0.003000	0.375	1.000	
1307130000	13G	Cranberry	1.000000	1.000	1.000	2
1307130001	13G	Cranberry-babyfood	1.000000	1.000	1.000	2
1307131000	13G	Cranberry, dried	1.000000	1.000	1.000	2
1307132000	13G	Cranberry, juice	1.000000	0.300	1.000	2
1307132001	13G	Cranberry, juice-babyfood	1.000000	0.300	1.000	2
0902135000	9B	Cucumber	1.000000	1.000	1.000	15
7000145000	70	Egg, whole	0.004900	0.500	1.000	
7000145001	70	Egg, whole-babyfood	0.004900	0.500	1.000	
7000146000	70	Egg, white	0.004900	0.500	1.000	
7000146001	70	Egg, white (solids)-babyfood	0.004900	0.500	1.000	
7000147000	70	Egg, yolk	0.004900	0.500	1.000	
7000147001	70	Egg, yolk-babyfood	0.004900	0.500	1.000	
9500153000	O	Fig	0.010000	1.000	1.000	
9500154000	O	Fig, dried	0.010000	1.000	1.000	
1400155000	14	Hazelnut	1.000000	1.000	1.000	55
1400156000	14	Hazelnut, oil	1.000000	1.600	1.000	55
0301165000	3A	Garlic, bulb	0.005000	1.000	1.000	

0301165001	3A	Garlic, bulb-babyfood	0.005000	1.000	1.000		
3200169000	32	Goat, meat	0.000500	0.500	1.000		
3200170000	32	Goat, meat byproducts	0.000500	0.500	1.000		
3200171000	32	Goat, fat	0.000500	0.500	1.000		
3200172000	32	Goat, kidney	0.000500	0.500	1.000		
3200173000	32	Goat, liver	0.000500	0.500	1.000		
1304175000	13D	Grape	1.000000	1.000	1.000	6	Grape
Full comment: Grape RDF							
1304176000	13D	Grape, juice	1.000000	1.000	1.000	43	
1304176001	13D	Grape, juice-babyfood	1.000000	1.000	1.000	43	
9500177000	O	Grape, leaves	1.000000	1.500	1.000	6	
9500178000	O	Grape, raisin	1.000000	1.000	1.000	45	
1304179000	13D	Grape, wine and sherry	1.000000	0.020	1.000	6	
1003180000	10C	Grapefruit	1.000000	1.000	1.000	17	
1003181000	10C	Grapefruit, juice	1.000000	1.170	1.000	20	
0603182000	6C	Guar, seed					
		110-Uncooked; Fresh or N/S; Cook Meth N/S	0.000630	1.000	1.000		
		120-Uncooked; Frozen; Cook Meth N/S	0.000630	1.000	1.000		
		130-Uncooked; Dried; Cook Meth N/S	0.000630	1.000	1.000		
		210-Cooked; Fresh or N/S; Cook Meth N/S	0.000630	1.000	1.000		
		211-Cooked; Fresh or N/S; Baked	0.000630	1.000	1.000		
		212-Cooked; Fresh or N/S; Boiled	0.000630	1.000	1.000		
		213-Cooked; Fresh or N/S; Fried	0.000630	1.000	1.000		
		214-Cooked; Fresh or N/S; Fried/baked	0.000630	1.000	1.000		
		221-Cooked; Frozen; Baked	0.000630	1.000	1.000		
		223-Cooked; Frozen; Fried	0.000630	1.000	1.000		
		230-Cooked; Dried; Cook Meth N/S	0.000630	1.000	1.000		
		240-Cooked; Canned; Cook Meth N/S	0.000630	1.000	1.000		
		250-Cooked; Cured etc; Cook Meth N/S	0.000630	1.000	1.000		
0603182001	6C	Guar, seed-babyfood	0.000630	1.000	1.000		
0502194000	5B	Kale	1.000000	0.830	1.000	25	
1304195000	13D	Kiwifruit, fuzzy	2.000000	0.150	1.000	13	
0501196000	5A	Kohlrabi	1.000000	0.940	1.000	10	
1002197000	10B	Kumquat	1.000000	1.000	1.000	40	
1002199000	10B	Lemon	1.000000	1.000	1.000	18	
1002200000	10B	Lemon, juice	1.000000	1.110	1.000	52	
1002200001	10B	Lemon, juice-babyfood	1.000000	1.110	1.000	52	
1002201000	10B	Lemon, peel	1.000000	15.000	1.000	18	
0603203000	6C	Lentil, seed					
		230-Cooked; Dried; Cook Meth N/S	0.000630	1.000	1.000		
		232-Cooked; Dried; Boiled	0.000630	1.000	1.000		
1002206000	10B	Lime	1.000000	1.000	1.000	40	
1002207000	10B	Lime, juice	1.000000	1.110	1.000	53	
1002207001	10B	Lime, juice-babyfood	1.000000	1.110	1.000	53	
3800221000	38	Meat, game	0.000500	0.500	1.000		
0502229000	5B	Mustard greens	1.000000	0.830	1.000	25	
1202230000	12B	Nectarine	1.000000	1.000	1.000	34	
0301237000	3A	Onion, bulb	0.002500	1.000	1.000	27	
0301237001	3A	Onion, bulb-babyfood	0.002500	1.000	1.000	27	
0301238000	3A	Onion, bulb, dried	0.002500	9.000	1.000		
0301238001	3A	Onion, bulb, dried-babyfood	0.002500	9.000	1.000		

1001240000	10A	Orange	1.000000	1.000	1.000	19
1001241000	10A	Orange, juice	1.000000	1.000	1.000	20
1001241001	10A	Orange, juice-babyfood	1.000000	1.000	1.000	20
1001242000	10A	Orange, peel	1.000000	15.000	1.000	19
0602255000	6B	Pea, succulent				
		110-Uncooked; Fresh or N/S; Cook Meth N/S	1.000000	1.000	1.000	51
		210-Cooked; Fresh or N/S; Cook Meth N/S	1.000000	1.000	1.000	51
		211-Cooked; Fresh or N/S; Baked	1.000000	1.000	1.000	51
		212-Cooked; Fresh or N/S; Boiled	1.000000	1.000	1.000	51
		213-Cooked; Fresh or N/S; Fried	1.000000	1.000	1.000	51
		221-Cooked; Frozen; Baked	1.000000	1.000	1.000	51
		222-Cooked; Frozen; Boiled	1.000000	1.000	1.000	51
		232-Cooked; Dried; Boiled	1.000000	1.000	1.000	51
		240-Cooked; Canned; Cook Meth N/S	1.000000	1.000	1.000	51
		242-Cooked; Canned; Boiled	1.000000	1.000	1.000	51
0602255001	6B	Pea, succulent-babyfood	1.000000	1.000	1.000	51
0603256000	6C	Pea, dry	0.000630	1.000	1.000	
0603256001	6C	Pea, dry-babyfood	0.000630	1.000	1.000	
0601257000	6A	Pea, edible podded, succulent	1.000000	1.000	1.000	51
0603258000	6C	Pea, pigeon, seed				
		210-Cooked; Fresh or N/S; Cook Meth N/S	0.000630	1.000	1.000	
		232-Cooked; Dried; Boiled	0.000630	1.000	1.000	
0602259000	6B	Pea, pigeon, succulent	1.000000	1.000	1.000	5
1202260000	12B	Peach				
		110-Uncooked; Fresh or N/S; Cook Meth N/S	1.000000	1.000	1.000	21
		120-Uncooked; Frozen; Cook Meth N/S	1.000000	1.000	1.000	21
		130-Uncooked; Dried; Cook Meth N/S	1.000000	1.000	1.000	21
		210-Cooked; Fresh or N/S; Cook Meth N/S	1.000000	0.500	1.000	21
		211-Cooked; Fresh or N/S; Baked	1.000000	0.500	1.000	21
		213-Cooked; Fresh or N/S; Fried	1.000000	0.500	1.000	21
		223-Cooked; Frozen; Fried	1.000000	0.500	1.000	21
		230-Cooked; Dried; Cook Meth N/S	1.000000	0.500	1.000	21
		240-Cooked; Canned; Cook Meth N/S	1.000000	0.520	1.000	16
1202260001	12B	Peach-babyfood	1.000000	0.520	1.000	16
1202261000	12B	Peach, dried	1.000000	7.000	1.000	21
1202261001	12B	Peach, dried-babyfood	1.000000	7.000	1.000	21
1202262000	12B	Peach, juice	1.000000	0.300	1.000	16
1202262001	12B	Peach, juice-babyfood	1.000000	0.300	1.000	16
9500263000	O	Peanut	0.007000	1.000	1.000	
9500264000	O	Peanut, butter	0.013500	1.000	1.000	
9500265000	O	Peanut, oil	0.007000	2.000	1.000	
1100266000	11	Pear				
		110-Uncooked; Fresh or N/S; Cook Meth N/S	1.000000	1.000	1.000	31
		210-Cooked; Fresh or N/S; Cook Meth N/S	1.000000	0.150	1.000	31
		211-Cooked; Fresh or N/S; Baked	1.000000	0.150	1.000	31

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                  240-Cooked; Canned; Cook Meth N/S
                                                0.000700   0.150  1.000
1100266001 11   Pear-babyfood                   1.000000   0.150  1.000  31
1100267000 11   Pear, dried                     1.000000   1.000  1.000  31
1100268000 11   Pear, juice
                  110-Uncooked; Fresh or N/S; Cook Meth N/S
                                                0.000700   0.150  1.000
                  120-Uncooked; Frozen; Cook Meth N/S
                                                0.000700   0.150  1.000
                  130-Uncooked; Dried; Cook Meth N/S
                                                0.000700   0.150  1.000
                  211-Cooked; Fresh or N/S; Baked
                                                0.000700   0.150  1.000
                  230-Cooked; Dried; Cook Meth N/S
                                                0.000700   0.150  1.000
                  240-Cooked; Canned; Cook Meth N/S
                                                0.000700   0.150  1.000
1100268001 11   Pear, juice-babyfood            0.000700   0.150  1.000
1400269000 14   Pecan                           1.000000   1.000  1.000  56
0802270000 8B   Pepper, bell
                  110-Uncooked; Fresh or N/S; Cook Meth N/S
                                                1.000000   1.000  1.000  23
                  150-Uncooked; Cured etc; Cook Meth N/S
                                                1.000000   1.000  1.000  23
                  204-Cooked; FF N/A; Fried/baked
                                                1.000000   0.820  1.000  23  New
FF
         Full comment: New FF -- PF of 0.82 added by KDT
                  210-Cooked; Fresh or N/S; Cook Meth N/S
                                                1.000000   1.000  1.000  23
                  211-Cooked; Fresh or N/S; Baked
                                                1.000000   0.820  1.000  23
                  212-Cooked; Fresh or N/S; Boiled
                                                1.000000   1.190  1.000  23
                  213-Cooked; Fresh or N/S; Fried
                                                1.000000   1.000  1.000  23
                  214-Cooked; Fresh or N/S; Fried/baked
                                                1.000000   0.820  1.000  23
                  215-Cooked; Fresh or N/S; Boiled/baked
                                                1.000000   1.000  1.000  23
                  220-Cooked; Frozen; Cook Meth N/S
                                                1.000000   1.190  1.000  23  New
FF
         Full comment: New FF -- PF of 1.19 added by KDT
                  221-Cooked; Frozen; Baked     1.000000   0.820  1.000  23
                  222-Cooked; Frozen; Boiled    1.000000   1.190  1.000  23
                  223-Cooked; Frozen; Fried     1.000000   1.000  1.000  23
                  232-Cooked; Dried; Boiled     1.000000   1.190  1.000  23
                  240-Cooked; Canned; Cook Meth N/S
                                                1.000000   1.000  1.000  23
                  242-Cooked; Canned; Boiled    1.000000   1.190  1.000  23
                  250-Cooked; Cured etc; Cook Meth N/S
                                                1.000000   1.000  1.000  23
                  252-Cooked; Cured etc; Boiled 1.000000   1.190  1.000  23
0802270001 8B   Pepper, bell-babyfood           1.000000   1.000  1.000  23
0802271000 8B   Pepper, bell, dried             1.000000   1.000  1.000  23
0802271001 8B   Pepper, bell, dried-babyfood    1.000000   1.000  1.000  23
0802272000 8BC  Pepper, nonbell
                  100-Uncooked; FF N/A; Cook Meth N/S
                                                1.000000   1.000  1.000  23
                  110-Uncooked; Fresh or N/S; Cook Meth N/S
                                                1.000000   1.000  1.000  23
                  140-Uncooked; Canned; Cook Meth N/S
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                                              1.000000   1.000  1.000  23
                   150-Uncooked; Cured etc; Cook Meth N/S
                                              1.000000   1.000  1.000  23
                   204-Cooked; FF N/A; Fried/baked
                                              1.000000   0.820  1.000  23  New
FF
          Full comment: New FF -- PF of 0.82 added by KDT
                   210-Cooked; Fresh or N/S; Cook Meth N/S
                                              1.000000   1.000  1.000  23
                   211-Cooked; Fresh or N/S; Baked
                                              1.000000   0.820  1.000  23
                   212-Cooked; Fresh or N/S; Boiled
                                              1.000000   1.190  1.000  23
                   213-Cooked; Fresh or N/S; Fried
                                              1.000000   0.820  1.000  23
                   214-Cooked; Fresh or N/S; Fried/baked
                                              1.000000   0.820  1.000  23
                   215-Cooked; Fresh or N/S; Boiled/baked
                                              1.000000   1.190  1.000  23
                   220-Cooked; Frozen; Cook Meth N/S
                                              1.000000   1.190  1.000  23
                   221-Cooked; Frozen; Baked      1.000000   0.820  1.000  23
                   223-Cooked; Frozen; Fried      1.000000   1.190  1.000  23  New
FF
          Full comment: New FF -- PF of 1.19 added by KDT
                   230-Cooked; Dried; Cook Meth N/S
                                              1.000000   1.190  1.000  23
                   232-Cooked; Dried; Boiled      1.000000   1.190  1.000  23
                   240-Cooked; Canned; Cook Meth N/S
                                              1.000000   1.190  1.000  23
                   242-Cooked; Canned; Boiled     1.000000   1.190  1.000  23
                   243-Cooked; Canned; Fried      1.000000   1.190  1.000  23
                   250-Cooked; Cured etc; Cook Meth N/S
                                              1.000000   1.190  1.000  23
                   252-Cooked; Cured etc; Boiled  1.000000   1.190  1.000  23
0802272001 8BC  Pepper, nonbell-babyfood          1.000000   1.190  1.000  23
0802273000 8BC  Pepper, nonbell, dried            1.000000   1.000  1.000  23
9500275000 O    Peppermint                        2.000000   1.000  1.000
9500276000 O    Peppermint, oil                   2.000000  10.000  1.000
9500283000 O    Plantain                          1.000000   0.500  1.000   7
9500284000 O    Plantain, dried                   1.000000   3.900  1.000   7
1203285000 12C  Plum
                   110-Uncooked; Fresh or N/S; Cook Meth N/S
                                              1.000000   0.500  1.000  26  Peach
          Full comment: Peach cooking factor
                   210-Cooked; Fresh or N/S; Cook Meth N/S
                                              1.000000   0.500  1.000  26
                   240-Cooked; Canned; Cook Meth N/S
                                              1.000000   0.500  1.000  26
1203285001 12C  Plum-babyfood                     1.000000   0.500  1.000  26
1203286000 12C  Plum, prune, fresh                1.000000   1.000  1.000  26
1203286001 12C  Plum, prune, fresh-babyfood       1.000000   1.000  1.000  26
1203287000 12C  Plum, prune, dried                1.000000   1.000  1.000  50
1203287001 12C  Plum, prune, dried-babyfood       1.000000   1.000  1.000  50
1203288000 12C  Plum, prune, juice                1.000000   0.280  1.000  50
estima
    Full comment: estimated dilution factor
1203288001 12C  Plum, prune, juice-babyfood       1.000000   0.280  1.000  50
estima
    Full comment: estimated dilution factor
3400290000 34   Pork, meat                        0.000038   0.500  1.000
3400290001 34   Pork, meat-babyfood               0.000038   0.500  1.000
3400291000 34   Pork, skin                        0.000038   0.500  1.000
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3400292000	34	Pork, meat byproducts	0.000038	0.500	1.000		
3400292001	34	Pork, meat byproducts-babyfood	0.000038	0.500	1.000		
3400293000	34	Pork, fat	0.000038	0.500	1.000	30	
3400293001	34	Pork, fat-babyfood	0.000038	0.500	1.000	30	
3400294000	34	Pork, kidney	0.000038	0.500	1.000		
3400295000	34	Pork, liver	0.000038	0.500	1.000		
6000301000	60	Poultry, other, meat	0.000750	0.500	1.000		
6000302000	60	Poultry, other, liver	0.004900	0.500	1.000		
6000303000	60	Poultry, other, meat byproducts	0.004900	0.500	1.000		
6000304000	60	Poultry, other, fat	0.004900	0.500	1.000		
6000305000	60	Poultry, other, skin	0.004900	0.500	1.000		
1003307000	10C	Pummelo	1.000000	1.000	1.000	40	
0902308000	9B	Pumpkin	1.000000	1.000	1.000	15	
0902309000	9B	Pumpkin, seed	1.000000	1.000	1.000	15	
3900312000	39	Rabbit, meat	0.000500	0.500	1.000		
0101314000	1AB	Radish, roots	1.000000	1.000	1.000	22	
0101316000	1AB	Radish, Oriental, roots	1.000000	1.000	1.000	22	
0502318000	5B	Rape greens	1.000000	0.830	1.000	25	
0101327000	1AB	Rutabaga	1.000000	1.000	1.000	22	
0302338500	3B	Shallot, fresh leaves	0.005000	1.000	1.000		
3500339000	35	Sheep, meat	0.000500	0.500	1.000		
3500339001	35	Sheep, meat-babyfood	0.000500	0.500	1.000		
3500340000	35	Sheep, meat byproducts	0.000500	0.500	1.000		
3500341000	35	Sheep, fat	0.000500	0.500	1.000		
3500341001	35	Sheep, fat-babyfood	0.000500	0.500	1.000		
3500342000	35	Sheep, kidney	0.000500	0.500	1.000		
3500343000	35	Sheep, liver	0.000500	0.500	1.000		
1500344000	15	Sorghum, grain	0.001110	1.000	1.000		corn
A							
Full comment: corn AR							
1500345000	15	Sorghum, syrup	0.001110	0.050	1.000		corn
A							
Full comment: corn AR							
0600347000	6	Soybean, seed	0.002900	1.000	1.000		
0603348000	6C	Soybean, flour	0.002900	1.000	1.000		
0603348001	6C	Soybean, flour-babyfood	0.002900	1.000	1.000		
0600349000	6	Soybean, soy milk	0.002900	1.000	1.000		
0600349001	6	Soybean, soy milk-babyfood or in	0.002900	1.000	1.000		
0600350000	6	Soybean, oil	0.002900	0.140	1.000		
0600350001	6	Soybean, oil-babyfood	0.002900	0.140	1.000		
9500352000	O	Spearmint	2.000000	1.000	1.000		
9500353000	O	Spearmint, oil	2.000000	10.000	1.000		
1307359000	13G	Strawberry	1.000000	1.000	1.000	8	
1307359001	13G	Strawberry-babyfood	1.000000	1.000	1.000	8	
1307360000	13G	Strawberry, juice	1.000000	0.300	1.000	8	
1307360001	13G	Strawberry, juice-babyfood	1.000000	0.300	1.000	8	
2002364000	20B	Sunflower, seed	0.001150	1.000	1.000		
2002365000	20B	Sunflower, oil	0.001150	2.500	1.000		
2002365001	20B	Sunflower, oil-babyfood	0.001150	2.500	1.000		
0103366000	1CD	Sweet potato					
		210-Cooked; Fresh or N/S; Cook Meth N/S	1.000000	0.150	1.000	29	
		211-Cooked; Fresh or N/S; Baked	1.000000	0.150	1.000	29	
		212-Cooked; Fresh or N/S; Boiled	1.000000	0.150	1.000	29	
		213-Cooked; Fresh or N/S; Fried	1.000000	0.150	1.000	29	
		215-Cooked; Fresh or N/S; Boiled/baked	1.000000	0.150	1.000	29	
		240-Cooked; Canned; Cook Meth N/S	1.000000	0.150	1.000	29	
		242-Cooked; Canned; Boiled	1.000000	0.150	1.000	29	

0103366001	1CD	Sweet potato-babyfood	1.000000	0.150	1.000	29
1001369000	10A	Tangerine	1.000000	1.000	1.000	35
1001370000	10A	Tangerine, juice	1.000000	1.280	1.000	54
1500381000	15	Triticale, flour	0.003000	0.145	1.000	
1500381001	15	Triticale, flour-babyfood	0.003000	0.145	1.000	
5000382000	50	Turkey, meat	0.000750	0.500	1.000	
5000382001	50	Turkey, meat-babyfood	0.000750	0.500	1.000	
5000383000	50	Turkey, liver	0.004900	0.500	1.000	
5000383001	50	Turkey, liver-babyfood	0.004900	0.500	1.000	
5000384000	50	Turkey, meat byproducts	0.004900	0.500	1.000	
5000384001	50	Turkey, meat byproducts-babyfood	0.004900	0.500	1.000	
5000385000	50	Turkey, fat	0.004900	0.500	1.000	
5000385001	50	Turkey, fat-babyfood	0.004900	0.500	1.000	
5000386000	50	Turkey, skin	0.004900	0.500	1.000	
5000386001	50	Turkey, skin-babyfood	0.004900	0.500	1.000	
0101388000	1AB	Turnip, roots	1.000000	1.000	1.000	22
0502389000	5B	Turnip, greens	0.300000	0.830	1.000	25
1400391000	14	Walnut	1.000000	1.000	1.000	57
8601000000	86A	Water, direct, all sources	0.000120	7.000	1.000	58
8602000000	86B	Water, indirect, all sources	0.000120	7.000	1.000	58
1500401000	15	Wheat, grain				
		110-Uncooked; Fresh or N/S; Cook Meth N/S	0.003000	1.000	1.000	42
		120-Uncooked; Frozen; Cook Meth N/S	0.003000	1.000	1.000	42
		210-Cooked; Fresh or N/S; Cook Meth N/S	0.003000	0.860	1.000	42
		211-Cooked; Fresh or N/S; Baked	0.003000	0.860	1.000	42
		212-Cooked; Fresh or N/S; Boiled	0.003000	0.026	1.000	42
		213-Cooked; Fresh or N/S; Fried	0.003000	0.860	1.000	42
		214-Cooked; Fresh or N/S; Fried/baked	0.003000	0.860	1.000	42
		223-Cooked; Frozen; Fried	0.003000	0.860	1.000	42
		230-Cooked; Dried; Cook Meth N/S	0.003000	0.860	1.000	42
		231-Cooked; Dried; Baked	0.003000	0.860	1.000	42
		232-Cooked; Dried; Boiled	0.003000	0.026	1.000	42
		233-Cooked; Dried; Fried	0.003000	0.860	1.000	42
		240-Cooked; Canned; Cook Meth N/S	0.003000	0.026	1.000	42
1500401001	15	Wheat, grain-babyfood				
		211-Cooked; Fresh or N/S; Baked	0.003000	0.860	1.000	42
		230-Cooked; Dried; Cook Meth N/S	0.003000	0.860	1.000	42
		240-Cooked; Canned; Cook Meth N/S	0.003000	0.026	1.000	42
1500402000	15	Wheat, flour	0.003000	0.145	1.000	
1500402001	15	Wheat, flour-babyfood	0.003000	0.145	1.000	
1500403000	15	Wheat, germ	0.003000	2.700	1.000	
1500404000	15	Wheat, bran	0.003000	3.000	1.000	

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US EPA                                                        Ver. 3.18, 03-08-d
DEEM-FCID ACUTE Analysis for CHLORPYRIFOS-ACUTE          NHANES 2003-2008 2-Day
Residue file: ACUTE_NOH20FIXFOOD7JUNVC36POD (CONVERTED) -  QAd by KDT -- CPFW -- TAF
is 7.R08
Adjustment factor #2 NOT used.
Analysis Date: 04-29-2014/14:17:58    Residue file dated: 04-29-2014/12:49:54
RAC/FF intake summed over 24 hours
MC iterations = 2000; MC list in residue file; MC seed = 10; RNG = MS VB
Run Comment: "Food + Water (CPFW; TAF is 7); CFOS POD of 0.0036 Used"
===============================================================================
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Summary calculations--per capita:

	95th Percentile		99th Percentile		99.9th Percentile	
	Exposure	% aRfD	Exposure	% aRfD	Exposure	% aRfD
Total US Population:	0.000029	0.81	0.000062	1.73	0.000225	6.26
All Infants:	0.000047	1.31	0.000090	2.50	0.000231	6.40
Children 1-2:	0.000082	2.28	0.000183	5.07	0.000430	11.93
Children 3-5:	0.000061	1.70	0.000111	3.09	0.000311	8.63
Children 6-12:	0.000038	1.04	0.000072	2.01	0.000192	5.34
Youth 13-19:	0.000023	0.63	0.000044	1.21	0.000130	3.61
Adults 20-49:	0.000021	0.59	0.000042	1.17	0.000206	5.74
Adults 50-99:	0.000021	0.57	0.000043	1.20	0.000177	4.91
Female 13-49:	0.000021	0.57	0.000041	1.15	0.000146	4.06

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Filename: J:\1305765.000 (Dow Chlorpyrifos Aggregate Risk Assessment)\Residue
Files\Residue Files with NAWQA Inputs (final)\CHLORPYRIFOS_CHRONIC_DSA_WOFHEFXSBVC
(CONVERTED) - QAd by KDT -- H2O (CPFW) TAF is 2,7.R08
Chemical: Chlorpyrifos
RfD(Chronic): .0003 mg/kg bw/day  NOEL(Chronic): 0 mg/kg bw/day
RfD(Acute): .0036 mg/kg bw/day  NOEL(Acute):  0 mg/kg bw/day
Date created/last modified: 04-30-2014/09:47:21       Program ver. 3.16, 03-08-d
Comment: Food + Water (CPFW; TAF is 2.7); CFOS chronic POD of 0.0003 used
---------------------------------------------------------------------------------
   EPA     Crop                                   Def Res     Adj.Factors   Comment
   Code     Grp  Commodity Name                    (ppm)       #1    #2
---------- ---- ------------------------------  ----------  ------ ------  -------
0101052000 1A   Beet, sugar                        0.002000   1.000  1.000
0101052001 1A   Beet, sugar-babyfood               0.002000   1.000  1.000
0101053000 1A   Beet, sugar, molasses              0.002000   1.000  1.000
0101053001 1A   Beet, sugar, molasses-babyfood     0.002000   1.000  1.000
0101314000 1AB  Radish, roots                      0.001600   1.000  1.000
0101316000 1AB  Radish, Oriental, roots            0.001600   1.000  1.000  covere
            Full comment: covered by radish???
0101327000 1AB  Rutabaga                           0.001600   1.000  1.000
0101388000 1AB  Turnip, roots                      0.001600   1.000  1.000
0103366000 1CD  Sweet potato
                   210-Cooked; Fresh or N/S; Cook Meth N/S
                                                   0.001200   0.150  1.000
                   211-Cooked; Fresh or N/S; Baked
                                                   0.001200   0.150  1.000
                   212-Cooked; Fresh or N/S; Boiled
                                                   0.001200   0.150  1.000
                   213-Cooked; Fresh or N/S; Fried
                                                   0.001200   0.150  1.000
                   215-Cooked; Fresh or N/S; Boiled/baked
                                                   0.001200   0.150  1.000
                   240-Cooked; Canned; Cook Meth N/S
                                                   0.001200   0.150  1.000
                   242-Cooked; Canned; Boiled      0.001200   0.150  1.000
0103366001 1CD  Sweet potato-babyfood
                   211-Cooked; Fresh or N/S; Baked
                                                   0.001200   0.150  1.000
                   240-Cooked; Canned; Cook Meth N/S
                                                   0.001200   0.150  1.000
0301165000 3A   Garlic, bulb                       0.005000   1.000  1.000
0301165001 3A   Garlic, bulb-babyfood              0.005000   1.000  1.000
0301237000 3A   Onion, bulb                        0.001748   1.000  1.000
0301237001 3A   Onion, bulb-babyfood               0.001748   1.000  1.000
0301238000 3A   Onion, bulb, dried                 0.001748   9.000  1.000
0301238001 3A   Onion, bulb, dried-babyfood        0.001748   9.000  1.000
0302338500 3B   Shallot, fresh leaves              0.005000   1.000  1.000
0501061000 5A   Broccoli
                   110-Uncooked; Fresh or N/S; Cook Meth N/S
                                                   0.000600   1.000  1.000
                   210-Cooked; Fresh or N/S; Cook Meth N/S
                                                   0.000600   0.940  1.000
                   211-Cooked; Fresh or N/S; Baked
                                                   0.000600   0.940  1.000
                   212-Cooked; Fresh or N/S; Boiled
                                                   0.000600   0.940  1.000
                   213-Cooked; Fresh or N/S; Fried
                                                   0.000600   0.940  1.000
                   220-Cooked; Frozen; Cook Meth N/S
                                                   0.000600   0.940  1.000
                   221-Cooked; Frozen; Baked       0.000600   0.940  1.000
                   222-Cooked; Frozen; Boiled      0.000600   0.940  1.000
                   232-Cooked; Dried; Boiled       0.000600   0.940  1.000
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	242-Cooked; Canned; Boiled	0.000600	0.940	1.000
0501061001 5A	Broccoli-babyfood	0.000600	0.940	1.000
0501062000 5A	Broccoli, Chinese	0.000600	0.940	1.000
0501064000 5A	Brussels sprouts			
	110-Uncooked; Fresh or N/S; Cook Meth N/S	0.001100	1.000	1.000
	212-Cooked; Fresh or N/S; Boiled	0.001100	0.940	1.000
	222-Cooked; Frozen; Boiled	0.001100	0.940	1.000
0501069000 5A	Cabbage			
	110-Uncooked; Fresh or N/S; Cook Meth N/S	0.000260	1.000	1.000
	150-Uncooked; Cured etc; Cook Meth N/S	0.000260	1.000	1.000
	210-Cooked; Fresh or N/S; Cook Meth N/S	0.000260	0.830	1.000
	211-Cooked; Fresh or N/S; Baked	0.000260	0.830	1.000
	212-Cooked; Fresh or N/S; Boiled	0.000260	0.830	1.000
	213-Cooked; Fresh or N/S; Fried	0.000260	0.830	1.000
	221-Cooked; Frozen; Baked	0.000260	0.830	1.000
	230-Cooked; Dried; Cook Meth N/S	0.000260	0.830	1.000
	232-Cooked; Dried; Boiled	0.000260	0.830	1.000
	240-Cooked; Canned; Cook Meth N/S	0.000260	0.830	1.000
	242-Cooked; Canned; Boiled	0.000260	0.830	1.000
	245-Cooked; Canned; Boiled/baked	0.000260	0.830	1.000
	250-Cooked; Cured etc; Cook Meth N/S	0.000260	0.830	1.000
	255-Cooked; Cured etc; Boiled/baked	0.000260	0.830	1.000
0501071000 5A	Cabbage, Chinese, napa	0.001100	0.830	1.000
0501072000 5A	Cabbage, Chinese, mustard	0.001100	0.830	1.000
0501083000 5A	Cauliflower			
	110-Uncooked; Fresh or N/S; Cook Meth N/S	0.000220	1.000	1.000
	150-Uncooked; Cured etc; Cook Meth N/S	0.000220	1.000	1.000
	210-Cooked; Fresh or N/S; Cook Meth N/S	0.000220	0.940	1.000
	211-Cooked; Fresh or N/S; Baked	0.000220	0.940	1.000
	212-Cooked; Fresh or N/S; Boiled	0.000220	0.940	1.000
	213-Cooked; Fresh or N/S; Fried	0.000220	0.940	1.000
	221-Cooked; Frozen; Baked	0.000220	0.940	1.000
	222-Cooked; Frozen; Boiled	0.000220	0.940	1.000
	242-Cooked; Canned; Boiled	0.000220	0.940	1.000
	250-Cooked; Cured etc; Cook Meth N/S	0.000220	0.940	1.000
0501196000 5A	Kohlrabi	0.001100	0.940	1.000
0502063000 5B	Broccoli raab	0.004900	0.830	1.000
0502070000 5B	Cabbage, Chinese, bok choy			
	110-Uncooked; Fresh or N/S; Cook Meth N/S	0.004900	1.000	1.000
	150-Uncooked; Cured etc; Cook Meth N/S	0.004900	1.000	1.000
	210-Cooked; Fresh or N/S; Cook Meth N/S			

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                                             0.004900   0.830  1.000
                  213-Cooked; Fresh or N/S; Fried
                                             0.004900   0.830  1.000
                  221-Cooked; Frozen; Baked  0.004900   0.830  1.000
0502117000 5B  Collards                      0.012600   0.830  1.000
0502194000 5B  Kale                          0.004900   0.830  1.000
0502229000 5B  Mustard greens                0.004900   0.830  1.000
0502318000 5B  Rape greens                   0.004900   0.830  1.000
0502389000 5B  Turnip, greens                0.004900   0.830  1.000
0600347000 6   Soybean, seed                 0.002900   1.000  1.000
0600349000 6   Soybean, soy milk             0.002900   1.000  1.000
0600349001 6   Soybean, soy milk-babyfood or in  0.002900   1.000  1.000
0600350000 6   Soybean, oil                  0.002900   0.140  1.000
0600350001 6   Soybean, oil-babyfood         0.002900   0.140  1.000
0601043000 6A  Bean, snap, succulent         0.000060   0.580  1.000
0601043001 6A  Bean, snap, succulent-babyfood    0.000060   0.580  1.000
0601257000 6A  Pea, edible podded, succulent     0.000020   1.000  1.000
0602031000 6B  Bean, broad, succulent        0.000020   0.580  1.000  G.Bean
           Full comment: G.Bean cooking factor
0602033000 6B  Bean, cowpea, succulent       0.000020   0.580  1.000
0602037000 6B  Bean, lima, succulent         0.000020   0.580  1.000
0602255000 6B  Pea, succulent                0.000020   1.000  1.000
0602255001 6B  Pea, succulent-babyfood       0.000020   1.000  1.000
0602259000 6B  Pea, pigeon, succulent        0.000020   1.000  1.000
0603030000 6C  Bean, black, seed
                  210-Cooked; Fresh or N/S; Cook Meth N/S
                                             0.000250   1.000  1.000
                  230-Cooked; Dried; Cook Meth N/S
                                             0.000250   1.000  1.000
                  232-Cooked; Dried; Boiled  0.000250   1.000  1.000
0603032000 6C  Bean, broad, seed
                  210-Cooked; Fresh or N/S; Cook Meth N/S
                                             0.000250   1.000  1.000
                  230-Cooked; Dried; Cook Meth N/S
                                             0.000250   1.000  1.000
                  232-Cooked; Dried; Boiled  0.000250   1.000  1.000
0603034000 6C  Bean, cowpea, seed            0.000250   1.000  1.000
0603035000 6C  Bean,  great northern, seed
                  210-Cooked; Fresh or N/S; Cook Meth N/S
                                             0.000250   1.000  1.000
                  212-Cooked; Fresh or N/S; Boiled
                                             0.000250   1.000  1.000
                  230-Cooked; Dried; Cook Meth N/S
                                             0.000250   1.000  1.000
                  232-Cooked; Dried; Boiled  0.000250   1.000  1.000
                  242-Cooked; Canned; Boiled 0.000100   1.000  1.000
0603036000 6C  Bean, kidney, seed
                  210-Cooked; Fresh or N/S; Cook Meth N/S
                                             0.000250   1.000  1.000
                  211-Cooked; Fresh or N/S; Baked
                                             0.000250   1.000  1.000
                  212-Cooked; Fresh or N/S; Boiled
                                             0.000250   1.000  1.000
                  221-Cooked; Frozen; Baked  0.000250   1.000  1.000
                  232-Cooked; Dried; Boiled  0.000250   1.000  1.000
                  240-Cooked; Canned; Cook Meth N/S
                                             0.000100   1.000  1.000
                  242-Cooked; Canned; Boiled 0.000100   1.000  1.000
0603038000 6C  Bean, lima, seed
                  110-Uncooked; Fresh or N/S; Cook Meth N/S
                                             0.000250   1.000  1.000
                  210-Cooked; Fresh or N/S; Cook Meth N/S
                                             0.000250   1.000  1.000
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		222-Cooked; Frozen; Boiled	0.000250	1.000	1.000
		230-Cooked; Dried; Cook Meth N/S	0.000250	1.000	1.000
		232-Cooked; Dried; Boiled	0.000250	1.000	1.000
0603039000	6C	Bean, mung, seed			
		110-Uncooked; Fresh or N/S; Cook Meth N/S	0.000250	1.000	1.000
		210-Cooked; Fresh or N/S; Cook Meth N/S	0.000250	1.000	1.000
		212-Cooked; Fresh or N/S; Boiled	0.000250	1.000	1.000
		213-Cooked; Fresh or N/S; Fried	0.000250	1.000	1.000
		221-Cooked; Frozen; Baked	0.000250	1.000	1.000
		232-Cooked; Dried; Boiled	0.000250	1.000	1.000
		233-Cooked; Dried; Fried	0.000250	1.000	1.000
0603040000	6C	Bean, navy, seed			
		210-Cooked; Fresh or N/S; Cook Meth N/S	0.000250	1.000	1.000
		212-Cooked; Fresh or N/S; Boiled	0.000250	1.000	1.000
		230-Cooked; Dried; Cook Meth N/S	0.000250	1.000	1.000
		232-Cooked; Dried; Boiled	0.000250	1.000	1.000
		242-Cooked; Canned; Boiled	0.000100	1.000	1.000
0603041000	6C	Bean, pink, seed			
		212-Cooked; Fresh or N/S; Boiled	0.000250	1.000	1.000
		232-Cooked; Dried; Boiled	0.000250	1.000	1.000
0603042000	6C	Bean, pinto, seed			
		210-Cooked; Fresh or N/S; Cook Meth N/S	0.000250	1.000	1.000
		211-Cooked; Fresh or N/S; Baked	0.000250	1.000	1.000
		212-Cooked; Fresh or N/S; Boiled	0.000250	1.000	1.000
		213-Cooked; Fresh or N/S; Fried	0.000250	1.000	1.000
		221-Cooked; Frozen; Baked	0.000250	1.000	1.000
		230-Cooked; Dried; Cook Meth N/S	0.000250	1.000	1.000
		232-Cooked; Dried; Boiled	0.000250	1.000	1.000
0603098000	6C	Chickpea, seed			
		110-Uncooked; Fresh or N/S; Cook Meth N/S	0.000250	1.000	1.000
		210-Cooked; Fresh or N/S; Cook Meth N/S	0.000250	1.000	1.000
		212-Cooked; Fresh or N/S; Boiled	0.000250	1.000	1.000
		232-Cooked; Dried; Boiled	0.000250	1.000	1.000
		234-Cooked; Dried; Fried/baked	0.000250	1.000	1.000
0603098001	6C	Chickpea, seed-babyfood	0.000250	1.000	1.000
0603099000	6C	Chickpea, flour	0.000250	1.000	1.000
0603182000	6C	Guar, seed			
		110-Uncooked; Fresh or N/S; Cook Meth N/S	0.000250	1.000	1.000
		120-Uncooked; Frozen; Cook Meth N/S	0.000250	1.000	1.000
		130-Uncooked; Dried; Cook Meth N/S	0.000250	1.000	1.000
		210-Cooked; Fresh or N/S; Cook Meth N/S	0.000250	1.000	1.000
		211-Cooked; Fresh or N/S; Baked			

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                                                0.000250   1.000  1.000
                212-Cooked; Fresh or N/S; Boiled
                                                0.000250   1.000  1.000
                213-Cooked; Fresh or N/S; Fried
                                                0.000250   1.000  1.000
                214-Cooked; Fresh or N/S; Fried/baked
                                                0.000250   1.000  1.000
                221-Cooked; Frozen; Baked       0.000250   1.000  1.000
                223-Cooked; Frozen; Fried       0.000250   1.000  1.000
                230-Cooked; Dried; Cook Meth N/S
                                                0.000250   1.000  1.000
                240-Cooked; Canned; Cook Meth N/S
                                                0.000100   1.000  1.000
                250-Cooked; Cured etc; Cook Meth N/S
                                                0.000250   1.000  1.000
0603182001 6C   Guar, seed-babyfood             0.000250   1.000  1.000
0603203000 6C   Lentil, seed
                230-Cooked; Dried; Cook Meth N/S
                                                0.000250   1.000  1.000
                232-Cooked; Dried; Boiled       0.000250   1.000  1.000
0603256000 6C   Pea, dry                        0.000250   1.000  1.000
0603256001 6C   Pea, dry-babyfood               0.000250   1.000  1.000
0603258000 6C   Pea, pigeon, seed
                210-Cooked; Fresh or N/S; Cook Meth N/S
                                                0.000250   1.000  1.000
                232-Cooked; Dried; Boiled       0.000250   1.000  1.000
0603348000 6C   Soybean, flour                  0.002900   1.000  1.000
0603348001 6C   Soybean, flour-babyfood         0.002900   1.000  1.000
0802270000 8B   Pepper, bell
                110-Uncooked; Fresh or N/S; Cook Meth N/S
                                                0.009100   1.000  1.000
                150-Uncooked; Cured etc; Cook Meth N/S
                                                0.009100   1.000  1.000
                204-Cooked; FF N/A; Fried/baked
                                                0.009100   0.820  1.000  New FF
         Full comment: New FF -- PF of 0.82 assigned by KDT
                210-Cooked; Fresh or N/S; Cook Meth N/S
                                                0.009100   1.190  1.000
                211-Cooked; Fresh or N/S; Baked
                                                0.009100   0.820  1.000
                212-Cooked; Fresh or N/S; Boiled
                                                0.009100   1.190  1.000
                213-Cooked; Fresh or N/S; Fried
                                                0.009100   1.190  1.000
                214-Cooked; Fresh or N/S; Fried/baked
                                                0.009100   0.820  1.000
                215-Cooked; Fresh or N/S; Boiled/baked
                                                0.009100   1.190  1.000
                220-Cooked; Frozen; Cook Meth N/S
                                                0.009100   1.190  1.000  New FF
         Full comment: New FF -- Surrogated PF is correct
                221-Cooked; Frozen; Baked       0.009100   0.820  1.000
                222-Cooked; Frozen; Boiled      0.009100   1.190  1.000
                223-Cooked; Frozen; Fried       0.009100   1.190  1.000
                232-Cooked; Dried; Boiled       0.009100   1.190  1.000
                240-Cooked; Canned; Cook Meth N/S
                                                0.009100   1.190  1.000
                242-Cooked; Canned; Boiled      0.009100   1.190  1.000
                250-Cooked; Cured etc; Cook Meth N/S
                                                0.009100   1.190  1.000
                252-Cooked; Cured etc; Boiled   0.009100   1.190  1.000
0802270001 8B   Pepper, bell-babyfood           0.009100   1.190  1.000
0802271000 8B   Pepper, bell, dried             0.009100   1.000  1.000
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0802271001 8B   Pepper, bell, dried-babyfood       0.009100   1.000  1.000
0802272000 8BC  Pepper, nonbell
                   100-Uncooked; FF N/A; Cook Meth N/S
                                                   0.009100   1.000  1.000
                   110-Uncooked; Fresh or N/S; Cook Meth N/S
                                                   0.009100   1.000  1.000
                   140-Uncooked; Canned; Cook Meth N/S
                                                   0.009100   1.000  1.000
                   150-Uncooked; Cured etc; Cook Meth N/S
                                                   0.009100   1.000  1.000
                   204-Cooked; FF N/A; Fried/baked
                                                   0.009100   0.820  1.000  New FF
            Full comment: New FF -- PF of 0.82 assigned by KDT
                   210-Cooked; Fresh or N/S; Cook Meth N/S
                                                   0.009100   1.000  1.000
                   211-Cooked; Fresh or N/S; Baked
                                                   0.009100   0.820  1.000
                   212-Cooked; Fresh or N/S; Boiled
                                                   0.009100   1.190  1.000
                   213-Cooked; Fresh or N/S; Fried
                                                   0.009100   0.820  1.000
                   214-Cooked; Fresh or N/S; Fried/baked
                                                   0.009100   0.820  1.000
                   215-Cooked; Fresh or N/S; Boiled/baked
                                                   0.009100   1.190  1.000
                   220-Cooked; Frozen; Cook Meth N/S
                                                   0.009100   1.190  1.000
                   221-Cooked; Frozen; Baked       0.009100   0.820  1.000
                   223-Cooked; Frozen; Fried       0.009100   1.190  1.000  New FF
            Full comment: New FF -- PF of 1.19 assigned by KDT
                   230-Cooked; Dried; Cook Meth N/S
                                                   0.009100   1.190  1.000
                   232-Cooked; Dried; Boiled       0.009100   1.190  1.000
                   240-Cooked; Canned; Cook Meth N/S
                                                   0.009100   1.190  1.000
                   242-Cooked; Canned; Boiled      0.009100   1.190  1.000
                   243-Cooked; Canned; Fried       0.009100   1.190  1.000  Surrog
            Full comment: Surrogated PF is correct.
                   250-Cooked; Cured etc; Cook Meth N/S
                                                   0.009100   1.190  1.000
                   252-Cooked; Cured etc; Boiled   0.009100   1.190  1.000
0802272001 8BC  Pepper, nonbell-babyfood
                   240-Cooked; Canned; Cook Meth N/S
                                                   0.009100   1.000  1.000
0802273000 8BC  Pepper, nonbell, dried             0.009100   1.000  1.000
0902135000 9B   Cucumber                           0.000440   1.000  1.000
0902308000 9B   Pumpkin                            0.000440   1.000  1.000
0902309000 9B   Pumpkin, seed                      0.000440   1.000  1.000
1001106000 10A  Citron                             0.002800   1.000  1.000
1001107000 10A  Citrus hybrids                     0.002800   1.000  1.000
1001108000 10A  Citrus, oil                        0.002800   1.000  1.000
1001240000 10A  Orange                             0.000400   1.000  1.000
1001241000 10A  Orange, juice                      0.000300   1.000  1.000
1001241001 10A  Orange, juice-babyfood             0.000300   1.000  1.000
1001242000 10A  Orange, peel                       0.000400  15.000  1.000
1001369000 10A  Tangerine                          0.000400   1.000  1.000
1001370000 10A  Tangerine, juice                   0.000300   1.280  1.000
1002197000 10B  Kumquat                            0.002800   1.000  1.000
1002199000 10B  Lemon                              0.001000   1.000  1.000
1002200000 10B  Lemon, juice                       0.000700   1.110  1.000
1002200001 10B  Lemon, juice-babyfood              0.000700   1.110  1.000
1002201000 10B  Lemon, peel                        0.001000  15.000  1.000
1002206000 10B  Lime                               0.002800   1.000  1.000
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1002207000	10B	Lime, juice	0.002000	1.110	1.000	
1002207001	10B	Lime, juice-babyfood	0.002000	1.110	1.000	
1003180000	10C	Grapefruit	0.000190	1.000	1.000	
1003181000	10C	Grapefruit, juice	0.000400	1.170	1.000	
1003307000	10C	Pummelo	0.002800	1.000	1.000	
1100007000	11	Apple, fruit with peel				
		110-Uncooked; Fresh or N/S; Cook Meth N/S	0.000650	1.000	1.000	
		150-Uncooked; Cured etc; Cook Meth N/S	0.000650	1.000	1.000	
		211-Cooked; Fresh or N/S; Baked	0.000650	1.000	1.000	
		213-Cooked; Fresh or N/S; Fried	0.000650	1.000	1.000	
1100008000	11	Apple, peeled fruit				
		110-Uncooked; Fresh or N/S; Cook Meth N/S	0.000650	0.150	1.000	
		210-Cooked; Fresh or N/S; Cook Meth N/S	0.000650	0.150	1.000	
		211-Cooked; Fresh or N/S; Baked	0.000650	0.150	1.000	
		213-Cooked; Fresh or N/S; Fried	0.000650	0.150	1.000	
		221-Cooked; Frozen; Baked	0.000650	0.150	1.000	
		232-Cooked; Dried; Boiled	0.000650	0.150	1.000	
		240-Cooked; Canned; Cook Meth N/S	0.000650	0.150	1.000	
		241-Cooked; Canned; Baked	0.000650	0.150	1.000	
1100008001	11	Apple, peeled fruit-babyfood	0.000650	0.150	1.000	
1100009000	11	Apple, dried				
		130-Uncooked; Dried; Cook Meth N/S	0.000650	1.200	1.000	
		210-Cooked; Fresh or N/S; Cook Meth N/S	0.000650	1.200	1.000	
		211-Cooked; Fresh or N/S; Baked	0.000650	1.200	1.000	
		230-Cooked; Dried; Cook Meth N/S	0.000650	1.200	1.000	
1100009001	11	Apple, dried-babyfood	0.000650	1.200	1.000	
1100010000	11	Apple, juice	0.000850	0.150	1.000	Apple
		Full comment: Apple PDP data, modified				
1100010001	11	Apple, juice-babyfood	0.000850	0.150	1.000	
1100011000	11	Apple, sauce	0.000650	0.150	1.000	
1100011001	11	Apple, sauce-babyfood	0.000650	0.150	1.000	
1100266000	11	Pear				
		110-Uncooked; Fresh or N/S; Cook Meth N/S	0.000700	1.000	1.000	
		210-Cooked; Fresh or N/S; Cook Meth N/S	0.000700	0.150	1.000	
		211-Cooked; Fresh or N/S; Baked	0.000700	0.150	1.000	
		240-Cooked; Canned; Cook Meth N/S	0.000700	0.150	1.000	
1100266001	11	Pear-babyfood	0.000700	0.150	1.000	
1100267000	11	Pear, dried	0.000700	6.250	1.000	
1100268000	11	Pear, juice	0.000700	0.150	1.000	
1100268001	11	Pear, juice-babyfood	0.000700	0.150	1.000	
1201090000	12A	Cherry				
		110-Uncooked; Fresh or N/S; Cook Meth N/S	0.000400	1.000	1.000	
		120-Uncooked; Frozen; Cook Meth N/S	0.000400	1.000	1.000	
		210-Cooked; Fresh or N/S; Cook Meth N/S				

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                                          0.000400   1.160  1.000
                 211-Cooked; Fresh or N/S; Baked
                                          0.000400   1.150  1.000
                 213-Cooked; Fresh or N/S; Fried
                                          0.000400   1.160  1.000
                 223-Cooked; Frozen; Fried        0.000400   1.150  1.000
                 240-Cooked; Canned; Cook Meth N/S
                                          0.000400   0.590  1.000
                 241-Cooked; Canned; Baked        0.000400   0.590  1.000
1201090001 12A  Cherry-babyfood
                 211-Cooked; Fresh or N/S; Baked
                                          0.000400   1.160  1.000  New FF
            Full comment: New FF -- PF of 1.16 assigned by KDT
                 240-Cooked; Canned; Cook Meth N/S
                                          0.000400   0.590  1.000
1201091000 12A  Cherry, juice                    0.000400   0.300  1.000
1201091001 12A  Cherry, juice-babyfood           0.000400   0.300  1.000
1202230000 12B  Nectarine                        0.001300   1.000  1.000
1202260000 12B  Peach
                 110-Uncooked; Fresh or N/S; Cook Meth N/S
                                          0.003800   1.000  1.000
                 120-Uncooked; Frozen; Cook Meth N/S
                                          0.003800   1.000  1.000
                 130-Uncooked; Dried; Cook Meth N/S
                                          0.003800   1.000  1.000
                 210-Cooked; Fresh or N/S; Cook Meth N/S
                                          0.003800   0.500  1.000
                 211-Cooked; Fresh or N/S; Baked
                                          0.003800   0.500  1.000
                 213-Cooked; Fresh or N/S; Fried
                                          0.003800   0.500  1.000
                 223-Cooked; Frozen; Fried        0.003800   0.500  1.000
                 230-Cooked; Dried; Cook Meth N/S
                                          0.003800   0.500  1.000
                 240-Cooked; Canned; Cook Meth N/S
                                          0.003800   0.520  1.000
1202260001 12B  Peach-babyfood                   0.003800   0.520  1.000
1202261000 12B  Peach, dried                     0.003800   7.000  1.000
1202261001 12B  Peach, dried-babyfood            0.003800   7.000  1.000
1202262000 12B  Peach, juice                     0.003800   0.300  1.000
1202262001 12B  Peach, juice-babyfood            0.003800   0.300  1.000
1203285000 12C  Plum
                 110-Uncooked; Fresh or N/S; Cook Meth N/S
                                          0.002000   1.000  1.000
                 210-Cooked; Fresh or N/S; Cook Meth N/S
                                          0.002000   0.500  1.000
                 240-Cooked; Canned; Cook Meth N/S
                                          0.002000   0.500  1.000
1203285001 12C  Plum-babyfood                    0.002000   0.500  1.000
1203286000 12C  Plum, prune, fresh               0.002000   1.000  1.000
1203286001 12C  Plum, prune, fresh-babyfood      0.002000   1.000  1.000
1203287000 12C  Plum, prune, dried               0.000400   1.000  1.000
1203287001 12C  Plum, prune, dried-babyfood      0.000400   1.000  1.000
1203288000 12C  Plum, prune, juice               0.000400   0.280  1.000  estima
            Full comment: estimated dilution factor
1203288001 12C  Plum, prune, juice-babyfood      0.000400   0.280  1.000  estima
            Full comment: estimated dilution factor
1304175000 13D  Grape                            0.000240   1.000  1.000
1304176000 13D  Grape, juice                     0.000100   1.000  1.000
1304176001 13D  Grape, juice-babyfood            0.000100   1.000  1.000
1304179000 13D  Grape, wine and sherry           0.000240   0.020  1.000
1304195000 13D  Kiwifruit, fuzzy                 0.020000   0.150  1.000  tolera
            Full comment: tolerance
```

```
1307130000 13G  Cranberry                          0.006800   1.000  1.000
1307130001 13G  Cranberry-babyfood                 0.006800   1.000  1.000
1307131000 13G  Cranberry, dried                   0.006800   1.000  1.000
1307132000 13G  Cranberry, juice                   0.006800   0.300  1.000
1307132001 13G  Cranberry, juice-babyfood          0.006800   0.300  1.000
1307359000 13G  Strawberry                         0.000360   1.000  1.000
1307359001 13G  Strawberry-babyfood                0.000360   1.000  1.000
1307360000 13G  Strawberry, juice                  0.000360   0.300  1.000
1307360001 13G  Strawberry, juice-babyfood         0.000360   0.300  1.000
1400003000 14   Almond                             0.001800   1.000  1.000
1400003001 14   Almond-babyfood                    0.001800   1.000  1.000
1400004000 14   Almond, oil                        0.001800   2.000  1.000
1400004001 14   Almond, oil-babyfood               0.001800   2.000  1.000
1400155000 14   Hazelnut                           0.001400   1.000  1.000
1400156000 14   Hazelnut, oil                      0.001400   1.600  1.000
1400269000 14   Pecan                              0.002700   1.000  1.000
1400391000 14   Walnut                             0.003200   1.000  1.000
1500120000 15   Corn, field, flour                 0.001110   0.220  1.000  Brocco
            Full comment: Broccoli Cooking factor
1500120001 15   Corn, field, flour-babyfood        0.001110   0.220  1.000
1500121000 15   Corn, field, meal                  0.001110   0.220  1.000
1500121001 15   Corn, field, meal-babyfood         0.001110   0.220  1.000
1500122000 15   Corn, field, bran                  0.001110   0.220  1.000
1500123000 15   Corn, field, starch                0.001110   0.220  1.000
1500123001 15   Corn, field, starch-babyfood       0.001110   0.220  1.000
1500124000 15   Corn, field, syrup                 0.001110   0.050  1.000
1500124001 15   Corn, field, syrup-babyfood        0.001110   0.050  1.000
1500125000 15   Corn, field, oil                   0.001110   4.500  1.000
1500125001 15   Corn, field, oil-babyfood          0.001110   4.500  1.000
1500127000 15   Corn, sweet                        0.000150   0.940  1.000
1500127001 15   Corn, sweet-babyfood               0.000150   0.940  1.000
1500344000 15   Sorghum, grain                     0.001110   1.000  1.000  corn A
            Full comment: corn AR
1500345000 15   Sorghum, syrup                     0.001110   0.050  1.000
1500381000 15   Triticale, flour                   0.003000   0.145  1.000  Wheat
            Full comment: Wheat ARs
1500381001 15   Triticale, flour-babyfood          0.003000   0.145  1.000
1500401000 15   Wheat, grain
                   110-Uncooked; Fresh or N/S; Cook Meth N/S
                                                   0.003000   0.860  1.000
                   120-Uncooked; Frozen; Cook Meth N/S
                                                   0.003000   0.860  1.000
                   210-Cooked; Fresh or N/S; Cook Meth N/S
                                                   0.003000   0.860  1.000
                   211-Cooked; Fresh or N/S; Baked
                                                   0.003000   0.860  1.000
                   212-Cooked; Fresh or N/S; Boiled
                                                   0.003000   0.026  1.000
                   213-Cooked; Fresh or N/S; Fried
                                                   0.003000   0.860  1.000
                   214-Cooked; Fresh or N/S; Fried/baked
                                                   0.003000   0.860  1.000
                   223-Cooked; Frozen; Fried       0.003000   0.860  1.000
                   230-Cooked; Dried; Cook Meth N/S
                                                   0.003000   0.860  1.000
                   231-Cooked; Dried; Baked        0.003000   0.860  1.000
                   232-Cooked; Dried; Boiled       0.003000   0.026  1.000
                   233-Cooked; Dried; Fried        0.003000   0.860  1.000
                   240-Cooked; Canned; Cook Meth N/S
                                                   0.003000   0.860  1.000
1500401001 15   Wheat, grain-babyfood
                   211-Cooked; Fresh or N/S; Baked
                                                   0.003000   0.860  1.000
```

		230-Cooked; Dried; Cook Meth N/S			
			0.003000	0.860	1.000
		240-Cooked; Canned; Cook Meth N/S			
			0.003000	0.026	1.000
1500402000	15	Wheat, flour	0.003000	0.145	1.000
1500402001	15	Wheat, flour-babyfood	0.003000	0.145	1.000
1500403000	15	Wheat, germ	0.003000	2.700	1.000
1500404000	15	Wheat, bran	0.003000	3.000	1.000
2002364000	20B	Sunflower, seed	0.001150	1.000	1.000
2002365000	20B	Sunflower, oil	0.001150	2.500	1.000
2002365001	20B	Sunflower, oil-babyfood	0.001150	2.500	1.000
2003128000	20C	Cottonseed, oil	0.003000	0.375	1.000
2003128001	20C	Cottonseed, oil-babyfood	0.003000	0.375	1.000
3100044000	31	Beef, meat	0.001400	0.500	1.000
3100044001	31	Beef, meat-babyfood	0.001400	0.500	1.000
3100045000	31	Beef, meat, dried	0.001400	1.920	1.000
3100046000	31	Beef, meat byproducts	0.001400	0.500	1.000
3100046001	31	Beef, meat byproducts-babyfood	0.001400	0.500	1.000
3100047000	31	Beef, fat	0.001400	0.500	1.000
3100047001	31	Beef, fat-babyfood	0.001400	0.500	1.000
3100048000	31	Beef, kidney	0.001400	0.500	1.000
3100049000	31	Beef, liver	0.001400	0.500	1.000
3100049001	31	Beef, liver-babyfood	0.001400	0.500	1.000
3200169000	32	Goat, meat	0.001400	0.500	1.000
3200170000	32	Goat, meat byproducts	0.001400	0.500	1.000
3200171000	32	Goat, fat	0.001400	0.500	1.000
3200172000	32	Goat, kidney	0.001400	0.500	1.000
3200173000	32	Goat, liver	0.001400	0.500	1.000
3400290000	34	Pork, meat	0.000038	0.500	1.000
3400290001	34	Pork, meat-babyfood	0.000038	0.500	1.000
3400291000	34	Pork, skin	0.000038	0.500	1.000
3400292000	34	Pork, meat byproducts	0.000038	0.500	1.000
3400292001	34	Pork, meat byproducts-babyfood	0.000038	0.500	1.000
3400293000	34	Pork, fat	0.000755	0.500	1.000
3400293001	34	Pork, fat-babyfood	0.000038	0.500	1.000
3400294000	34	Pork, kidney	0.000038	0.500	1.000
3400295000	34	Pork, liver	0.000038	0.500	1.000
3500339000	35	Sheep, meat	0.001400	0.500	1.000
3500339001	35	Sheep, meat-babyfood	0.001400	0.500	1.000
3500340000	35	Sheep, meat byproducts	0.001400	0.500	1.000
3500341000	35	Sheep, fat	0.001400	0.500	1.000
3500341001	35	Sheep, fat-babyfood	0.001400	0.500	1.000
3500342000	35	Sheep, kidney	0.001400	0.500	1.000
3500343000	35	Sheep, liver	0.001400	0.500	1.000
3800221000	38	Meat, game	0.001400	0.500	1.000
3900312000	39	Rabbit, meat	0.001400	0.500	1.000
4000093000	40	Chicken, meat	0.000750	0.500	1.000
4000093001	40	Chicken, meat-babyfood	0.000750	0.500	1.000
4000094000	40	Chicken, liver	0.004900	0.500	1.000
4000095000	40	Chicken, meat byproducts	0.004900	0.500	1.000
4000095001	40	Chicken, meat byproducts-babyfoo	0.004900	0.500	1.000
4000096000	40	Chicken, fat	0.004900	0.500	1.000
4000096001	40	Chicken, fat-babyfood	0.004900	0.500	1.000
4000097000	40	Chicken, skin	0.004900	0.500	1.000
4000097001	40	Chicken, skin-babyfood	0.004900	0.500	1.000
5000382000	50	Turkey, meat	0.000750	0.500	1.000
5000382001	50	Turkey, meat-babyfood	0.000750	0.500	1.000
5000383000	50	Turkey, liver	0.004900	0.500	1.000
5000383001	50	Turkey, liver-babyfood	0.004900	0.500	1.000
5000384000	50	Turkey, meat byproducts	0.004900	0.500	1.000
5000384001	50	Turkey, meat byproducts-babyfood	0.004900	0.500	1.000
5000385000	50	Turkey, fat	0.004900	0.500	1.000
5000385001	50	Turkey, fat-babyfood	0.004900	0.500	1.000

5000386000 50	Turkey, skin	0.004900	0.500	1.000	
5000386001 50	Turkey, skin-babyfood	0.004900	0.500	1.000	
6000301000 60	Poultry, other, meat	0.000750	0.500	1.000	
6000302000 60	Poultry, other, liver	0.004900	0.500	1.000	
6000303000 60	Poultry, other, meat byproducts	0.004900	0.500	1.000	
6000304000 60	Poultry, other, fat	0.004900	0.500	1.000	
6000305000 60	Poultry, other, skin	0.004900	0.500	1.000	
7000145000 70	Egg, whole	0.004900	0.500	1.000	
7000145001 70	Egg, whole-babyfood	0.004900	0.500	1.000	
7000146000 70	Egg, white	0.004900	0.500	1.000	
7000146001 70	Egg, white (solids)-babyfood	0.004900	0.500	1.000	
7000147000 70	Egg, yolk	0.004900	0.500	1.000	
7000147001 70	Egg, yolk-babyfood	0.004900	0.500	1.000	
8601000000 86A	Water, direct, all sources	0.000003	2.700	1.000	
8602000000 86B	Water, indirect, all sources	0.000003	2.700	1.000	
9500019000 O	Asparagus				
	110-Uncooked; Fresh or N/S; Cook Meth N/S	0.004500	1.000	1.000	
	212-Cooked; Fresh or N/S; Boiled	0.004500	0.940	1.000	Brocco
	Full comment: Broccoli cooking factor				
	213-Cooked; Fresh or N/S; Fried	0.004500	0.940	1.000	
	222-Cooked; Frozen; Boiled	0.004500	0.940	1.000	
	242-Cooked; Canned; Boiled	0.000700	0.940	1.000	
9500023000 O	Banana	0.002000	1.000	1.000	
9500023001 O	Banana-babyfood	0.002000	1.000	1.000	
9500024000 O	Banana, dried	0.002000	3.900	1.000	
9500024001 O	Banana, dried-babyfood	0.002000	3.900	1.000	
9500153000 O	Fig	0.010000	1.000	1.000	
9500154000 O	Fig, dried	0.010000	1.000	1.000	
9500177000 O	Grape, leaves	0.000240	1.500	1.000	
9500178000 O	Grape, raisin	0.000200	1.000	1.000	
9500263000 O	Peanut	0.000350	1.000	1.000	
9500264000 O	Peanut, butter	0.013500	1.000	1.000	
9500265000 O	Peanut, oil	0.000350	2.000	1.000	
9500275000 O	Peppermint	2.000000	1.000	1.000	
9500276000 O	Peppermint, oil	2.000000	10.000	1.000	
9500283000 O	Plantain	0.002000	1.000	1.000	
9500284000 O	Plantain, dried	0.002000	3.900	1.000	
9500352000 O	Spearmint	2.000000	1.000	1.000	
9500353000 O	Spearmint, oil	2.000000	10.000	1.000	

```
US EPA                                                           Ver. 3.16, 03-08-d
DEEM-FCID Chronic analysis for CHLORPYRIFOS                 NHANES 2003-2008 2-day
Residue file name: J:\1305765.000 (Dow Chlorpyrifos Aggregate Risk
Assessment)\Residue Files\Residue Files with NAWQA Inputs
(final)\CHLORPYRIFOS_CHRONIC_DSA_WOFHEFXSBVC (CONVERTED) - QAd by KDT -- H2O (CPFW)
TAF is 2,7.R08
                                                 Adjustment factor #2 NOT used.
Analysis Date 04-30-2014/09:50:59     Residue file dated: 04-30-2014/09:47:21
Reference dose (RfD, Chronic) = .0003 mg/kg bw/day
COMMENT 1: Food + Water (CPFW; TAF is 2.7); CFOS chronic POD of 0.0003 used
===============================================================================
                    Total exposure by population subgroup
-------------------------------------------------------------------------------
```

Population Subgroup	Total Exposure: mg/kg body wt/day	Total Exposure: Percent of Rfd
Total US Population	0.000009	3.1%
Hispanic	0.000010	3.5%
Non-Hisp-White	0.000009	3.0%
Non-Hisp-Black	0.000009	2.9%
Non-Hisp-Other	0.000010	3.5%
Nursing Infants	0.000008	2.5%
Non-Nursing Infants	0.000016	5.3%
Female 13+ PREG	0.000008	2.7%
Children 1-6	0.000023	7.8%
Children 7-12	0.000012	4.1%
Male 13-19	0.000008	2.6%
Female 13-19/NP	0.000007	2.3%
Male 20+	0.000008	2.6%
Female 20+/NP	0.000007	2.4%
Seniors 55+	0.000007	2.5%
All Infants	0.000013	4.5%
Female 13-50	0.000007	2.3%
Children 1-2	0.000028	9.3%
Children 3-5	0.000022	7.2%
Children 6-12	0.000013	4.4%
Youth 13-19	0.000007	2.4%
Adults 20-49	0.000007	2.5%
Adults 50-99	0.000008	2.5%
Female 13-49	0.000007	2.3%

To: Schwab, Justin[schwab.justin@epa.gov]
From: Vaden, Stephen - OGC
Sent: Tue 3/7/2017 4:02:30 PM
Subject: Chlorpyrifos One-Pager
removed.txt
Revised Chlorpyrifos Revocation Questions_March 7 final.docx

Justin,

Attached, please find a brief document outlining USDA's concerns in bullet form. As always, I am happy to discuss any of the points or put your staff in contact with our wonderful career people. They and I are willing to assist you in any way.

Stephen

Stephen Alexander Vaden

U.S. Department of Agriculture

Office of the General Counsel

Senior Adviser to the Office of General Counsel

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' 202-720-3351 (Voice)

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To: Schwab, Justin[schwab.justin@epa.gov]
From: Vaden, Stephen - OGC
Sent: Thur 2/9/2017 11:31:24 PM
Subject: USDA Comment Filed January 17, 2017
removed.txt
USDA Public Comments on Chlorpyrifos 2017-01-17.pdf

Stephen Alexander Vaden

U.S. Department of Agriculture

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RESEARCH ARTICLE

Chlorpyrifos PBPK/PD model for multiple routes of exposure

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Abstract

1. Chlorpyrifos (CPF) is an important pesticide used to control crop insects. Human Exposures to CPF will occur primarily through oral exposure to residues on foods. A physiologically based pharmacokinetic/pharmacodynamic (PBPK/PD) model has been developed that describes the relationship between oral, dermal and inhalation doses of CPF and key events in the pathway for cholinergic effects. The model was built on a prior oral model that addressed age-related changes in metabolism and physiology. This multi-route model was developed in rats and humans to validate all scenarios in a parallelogram design.
2. Critical biological effects from CPF exposure require metabolic activation to CPF oxon, and small amounts of metabolism in tissues will potentially have a great effect on pharmacokinetics and pharmacodynamic outcomes. Metabolism (bioactivation and detoxification) was therefore added in diaphragm, brain, lung and skin compartments. Pharmacokinetic data are available for controlled human exposures via the oral and dermal routes and from oral and inhalation studies in rats. The validated model was then used to determine relative dermal versus inhalation uptake from human volunteers exposed to CPF in an indoor scenario.

Keywords

Chlorpyrifos, multi-route, PBPK

History

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Introduction

More than a decade has gone by since the original physiologically based pharmacokinetic and pharmacodynamic (PBPK/PD) model for chlorpyrifos (CPF) was first published (Timchalk et al., 2002b). The last 10 years has seen expansion of this model's ability to assess oral exposures in rats and humans. Important advancements in model parameterization have encompassed the inclusion of measured and further validated parameters, the assessment of data across lifestages, and statistical evaluation of the model combined with assessment of the effects of inter-individual variability in human physiology on exposure outcome (Busby-Hjerpe et al., 2010; Garabrant et al., 2009; Hinderliter et al., 2011; Poet et al., 2003; Price et al., 2011; Smith et al., 2009, 2011, 2014; Timchalk & Poet, 2008; Timchalk et al., 2002a). The CPF PBPK/PD model has at its foundation a great deal of human and rat exposure data.

Exposures to any chemical can be through multiple routes, for CPF oral, dermal and inhalation are possible. The dermal absorption is low, measured at less than 2% of an applied dose in a controlled human study (Nolan et al., 1984) and inhalation is also likely to be low due to a lack of volatility. Crop residue and dietary data and modeling suggest low level exposures to CPF (Hinderliter et al., 2011; Price et al., 2011). However, dermal and inhalation routes of exposure may be important for occupational exposure during manufacture, formulation or use by agricultural workers. Studies have found CPF residues in home air and dust samples, so residential exposures may likewise include oral, inhalation and dermal routes (Bradman et al., 2007; Morgan & Jones, 2013), but the oral route likely accounts for greater than 90% of CPF metabolites found in the general population (Egeghy et al., 2011).

Following oral exposures CPF is rapidly absorbed and metabolized both to the inactive 3,5,6-trichloro-2-pyridinol (TCPy) and to the active CPF-oxon (oxon). The pharmacodynamic outcome from CPF exposures is inhibition of acetylcholinesterase activity in the central and peripheral nervous system by the oxon metabolite (Padilla et al., 2005). Following dermal and inhalation routes, the pharmacokinetic and pharmacodynamic profile of the parent and metabolites are likely to be very different since first pass liver metabolism, which includes both bioactivation and detoxification are circumvented. Biomonitoring for CPF exposures generally involves either measurement of the stable metabolite TCPy or red blood cell (RBC) cholinesterase inhibition, but occasionally parent CPF has also been measured, but the external exposure leading to these internal measures may not be the same following non-oral routes. The multi-route PBPK model is a valuable tool to investigate the non-oral pharmacokinetics across species and the impact on these changes on the interpretation of biomonitoring results. There is a need for improved ways to understand and evaluate aggregate, multi-route exposures in humans beyond the very high dose studies in experimental animals. This multi-route

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PBPK model will be an invaluable way of estimating the impact of realistic exposures to CPF on cholinesterase inhibition.

Taking into account the plethora of data and using a parallelogram approach between the two species, a PBPK/PD model has now been constructed with the capability of modeling exposures via oral, dermal and inhalation routes and direct oral exposures to the active oxon metabolite has also been added. The development of this multi-route model was achieved by using rat oral and inhalation data and human oral and dermal data to simulate exposures through all four exposure routes. The multi-route model was built on the lifestage model platform (Smith et al., 2014), which has been independently validated (Hays & Kirman, 2013).

Materials and methods

Multi-route model structure

This model has been well validated over the last 14 years, built around the plethora of oral data in humans and rats and designed to fully describe the pharmacokinetic and pharmacodynamic outcomes from oral exposures (Hinderliter et al., 2011; Price et al., 2011; Smith et al., 2014; Timchalk et al., 2002a,b). The initial model published by Timchalk et al. (2002b), included rat and human data for the oral route and human dermal data. As is typical of such PBPK models, certain parameters were optimized to fit the data, included metabolic rate constants. Important updates to that original model have included measured CPF metabolic rate constants in human and rat hepatic tissue and rat intestinal tissue along with measured CPF-oxon metabolic rate constants (esterase) in rat and human plasma and hepatic tissues and in rat intestine (Poet et al., 2003; Smith et al., 2011). The measurement of intestinal metabolism facilitated the inclusion of metabolism in this portal of entry tissue. The lifestage model was an important advancement that included tissue growth over time (Smith et al., 2014) and accounts for growth in both human and rat tissues from birth until adulthood. The human model can also be used to model human variability, such as significant differences in body weight (BWT). The lifestage model platform used to develop the multi-route model thus included measured, not optimized, metabolic rate constants and tissue growth in two species. The remaining parameters that were optimized are noted in the text and Appendix. The routes within acslX and the Nelder–Mead algorithm were used for all optimizations. This report describes the addition exposure routes which have been made possible by the publication of new data.

CPF is highly metabolized by CYP450 enzymes via both the detoxification route to trichloropyridinol (TCPy) and to the active CPF oxon. Thus, metabolism is an important aspect of the PBPK model. Lowlevel metabolism has been measured in intestine (Poet et al., 2003), and brain tissue (Chambers & Chambers, 1989; Timchalk et al., 2012). Cholinesterase inhibition in diaphragm indicates that minor amounts of metabolism also occur in this tissue (Moser & Padilla, 1998). Thus, the conservative assumption that metabolism was 2% of hepatic was added to the brain, skin and diaphragm. Metabolic activity was also included in the lung compartment, as described below.

Human oral and dermal modeling

The main structure of the oral absorption model described in Timchalk et al. (2002b) has not changed since the original model was developed, but the lifestage model includes tissue-specific growth over the life of the rat or human. The oral model underpinning has been validated in rats and humans. The quick rise of the TCPy metabolite coupled with a delayed parent peak blood level indicated an oral absorption pattern that includes intestinal and stomach transfer and uptake (described in Timchalk et al., 2002b). While the rat includes some direct transport into the liver, described using a first-order transfer rate, very little absorption occurs in the stomach of humans (Hirtz, 1985), and a direct transfer to the liver did not result in a statistical improvement to the human oral data, so this rate has been set to zero for human simulations (see Appendix).

Skin has been included within the poorly perfused compartment of prior PBPK/PD model for CPF, but was not an exposure route. The skin in this equation includes total volume of skin (Equation (1)). Equations were added to describe the dermal route based on surface area exposed as a fraction of total body surface area (Equations (2)–(4)). All of the tissue growth equations are based on polynomials that were fit to age-specific tissue volumes (Smith et al., 2014; Young et al., 2009). Total volume of the skin is calculated based on BWT and constants ($VSK_{0\text{-}5}$; which are further described in Smith et al., 2014)

$$\mathrm{VSKC} = \mathrm{VSK0} + (\mathrm{VSK1} \times \mathrm{BWT}) + (\mathrm{VSK2} \times \mathrm{BWT}^2) + (\mathrm{VSK3} \times \mathrm{BWT}^3) + (\mathrm{VSK4} \times \mathrm{BWT}^4) + (\mathrm{VSK5} \times \mathrm{BWT}^5) \quad (1)$$

$$\mathrm{HT} = 19.994 + (5.5408 \times \mathrm{BWT}) - (0.0671 \times \mathrm{BWT}^2) + 0.003 \times \mathrm{BWT}^3 \quad (2)$$

$$\mathrm{TSA} = 71.81 \times (\mathrm{BWT}^{0.425}) \times (\mathrm{HT}^{0.725}) \quad (\text{Du Bois \& Du Bois, 1916}) \quad (3)$$

$$\mathrm{VSKCC} = \mathrm{VSKC} \times (\mathrm{SA}/\mathrm{TSA}) \quad (4)$$

Equations (2)–(4) define the surface area and volume of exposed skin based on growth. Height (HT) was fit to Centers for Disease Control (CDC) growth charts (Equation (2)), total surface area (TSA) of exposed skin was calculated based on BWT and height, thus TSA can be calculated across ages (Figure 1). The total volume that CPF is associated with (VSKCC) is define as the fraction of surface area exposed (SA) compared with TSA. This assumes that diffusion within the skin is limited to the skin immediately below the exposure site.

Thus, the dermal compartment itself comprises the volume of skin under the exposure site. Both CYP450 and esterase activity have been shown in skin (Hewitt et al., 2000; Oesch et al., 2007; Rolsted et al., 2008). A low level of metabolism in this compartment has an effect on total absorbed and cholinesterase inhibition profiles because the dermal route does not include the first pass metabolism observed following

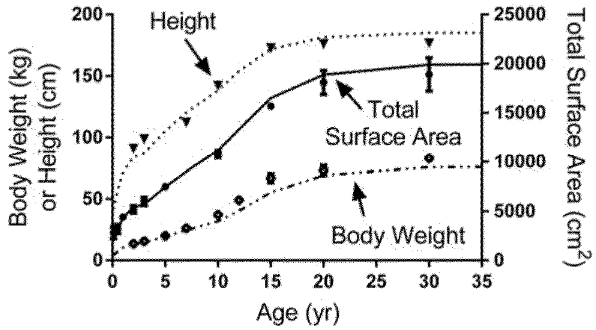

Figure 1. Total body surface area (TSA) mean ± 95% CI (male) based on age. Age-specific BWT was calculated as described in Smith et al. (2014), and an equation fit to height was developed based on centers for disease control and prevention growth charts for infants and children (http://www.cdc.gov/growthcharts/cdc_charts.htm). Data from NHANES 1999–2006 as reported in EPA. Exposures factors handbook are shown for comparison to height (triangles) and TSA (filled circles).

oral exposures. Metabolism within this compartment was set to 2% of hepatic based on per mg skin tissue in the following equation:

$$Vmaxskin = Vmaxliver \times (0.02) \times (VSKC) \quad (5)$$

Equation (5) is used for both CYP450-mediated metabolism to the oxon and to TCPy. Esterase metabolism in the skin has been reported to be 10–15% of liver activity (Beydon et al., 2010; Jewell et al., 2007), and esterase metabolism of the oxon to TCPy in the skin was therefore set to 15% of the liver.

The dose (mg) is considered to spread evenly over the SA exposed, for lower volumes, a volume term is included to account for loss over the course of exposure, this volume is set very large when exposures are considered to be constantly replenish or perfuse, and absorption is based on the permeability coefficient (Kp), which was optimized based on the data of Nolan et al. (1984). The Kp is based on Fick's law which describes flux at steady state based on the permeability and the concentration gradient across the membrane. Fick's law is conservative in assuming that flux is unidirectional, as given below

$$RASURF = -((((KP \times SA/1000) \times CSURF)) \times DZONE) \quad (6)$$

$$RADL = ((((KP \times SA/1000) \times CSURF)) \times DZONE) - RADLL - RMETDT - RMETDO \quad (7)$$

Equation (6) describes the rate of loss of CPF from the surface (CSURF). Equation (7) describes the rate of uptake of CPF into the skin compartment, and loss via metabolism to TCPy (RMETDT) and to CPF oxon (RMEDTDO) and absorption into the body (RADLL). DZONE is included as a switch to turn exposures off when the surface is washed. The concentration at the surface is described as diminishing when the exposure is limited.

Rat oral chlorpyrifos and chlorpyrifos oxon modeling

Pharmacokinetic and pharmacodynamic data from studies in rats are available following exposures to oral and inhalation routes for CPF as well as oral routes for the biologically active metabolite, CPF-oxon. Since the original model development, a single data set has been used to optimize the model (Timchalk et al., 2002b).

The data from the more recent studies by Marty et al. (2012) were used to validate the parameter optimizations for the most recent model. Marty et al. also include direct exposures to the oxon metabolite, and these data were used to optimize an oral absorption rate for the oxon, no other parameters were altered to describe the pharmacokinetics and pharmacodynamics of the oxon, further validating the pharmacodynamic aspects of the model.

Pulmonary modeling

The final potentially relevant route of exposure for CPF is inhalation. The change of volume of the lung with age has been previously defined in the lifestage model of Smith et al. (2014) (Equation (8)). CPF has very low volatility and is highly lipophilic, typical exposures to compounds with these properties typically exhibit pulmonary metabolism (Gerde et al., 1998).

Inhaled exposures were described using a similar mechanism as outlined by (O'Flaherty et al., 2001) for chromium, where a fraction of the chemical inhaled reaches deep lung tissue and is absorbed (Equation (9)) and the remainder is either metabolized in the nasal tissue or cleared from the nasal and conducting airways by mucociliary clearance and transferred to the gastrointestinal (GI) tract and absorbed as an oral dose (Equation (10))

$$VLC = VL0 + (VL1 \times BWTG) + (VL2 \times BWTG^2) \quad (8)$$

Like all of the tissue compartment volumes, lung volume is based on a polynomial that was fit to age-specific tissue volumes (Luecke et al., 2007; Smith et al., 2014). Age-specific lung volume is calculated based on BWT and constants ($VL_{0\text{-}2}$). Note – in this equation, BWT is multiplied by 100. The age-specific VLC is multiplied by BWT to determine final lung volume

$$RALINH = QALV \times FRACIN \times CI \quad (9)$$

$$RLUGI = (1 - FRACIN) \times CI \times QALV - AMUC \cdot KMUC \quad (10)$$

Equations (9) and (10) describe the uptake of CPF from an inhaled dose. Equation (8) describes the rate of uptake (RALINH) based on alveolar ventilation rate (QALV), the fraction of CPF available to the deep lung tissue (FRACIN) and the concentration in the air (CI). Equation (10) places all of the remaining potential dose into the GI tract based on a rate (KMUC) of transfer into that compartment.

The result of this model structure is the conservative assumption that all of the CPF in the inhaled volume of air will be deposited and absorbed either through the lung, nasal or the GI tissues. While exhalation is included in the model, the air partitioning of CPF is predicted to be so low that this route of elimination is close to zero. Also included in the lung compartment are B-esterases. Not included in the lung is detoxification of the oxon by PON1. Esterase activity is likely in the lung, but data were not available to parameterize the model, therefore no detoxification of the oxon in the lung is a conservative assumption.

In an inhalation exposure study (Hotchkiss et al., 2013), female CD rats were exposed to solid particulate CPF aerosols at 0, 3.7, 12.9, 22.1 or 53.5mg/m^3 and ChE activity in plasma, RBCs, brain and lung tissue was measured (average MMAD particle size of 1.8–1.9mm). Blood samples were collected after 2, 4 and 6h of exposure and 0.5, 1, 2, 4, 6, 12 and 24h after the end of 6h of exposure and blood levels of CPF, oxon and TCPy were determined. Urine was collected during the 6-h exposure and at post-exposure time intervals of 0–12, 12–24, 24–48 and 48–72h and was then analyzed to determine total excreted TCPy.

The Multiple-Path Particle Dosimetry Model (MPPD V2.1; Applied Research Associates, Inc., Albuquerque, NM) modeling software was used to calculate that 6.4% of inhaled particulate CPF will be deposited in the deep lung (alveolar gas exchange region). Of the deposited mass of CPF, 20% was optimized to be absorbed in the lung of the rat. The remainder of the deposited CPF was assumed to be cleared from the lung and absorbed through the GI tissue and a rate of transfer from the lung to the GI tissue was optimized based on the data. Using the same pulmonary dosimetry software (MPPD V2.1), 23% of inhaled CPF aerosol would be predicted to be deposited in the deep lung (alveolar gas exchange region) in a human breathing the same concentrations of CPF aerosol. The same 20% fraction of deposited CPF is assumed to be absorbed in human lung.

Consistent with the deposition of the majority of the dose in the nasal passages and the intrapulmonary conducting airways, a high level of pre-systemic metabolism is suggested by the data, equal to that observed for the liver. Thus, metabolism in this compartment was set equal to that in the liver on a per mg tissue basis.

Volunteer biomonitoring

A study was previously conducted with human volunteers to determine the absorbed dose of CPF following treatment of apartment carpeting with Empire*20 insecticide (Vaccaro et al., 1993). Empire*20 is a specialty insecticide used to control numerous pests in and around households and other structures, consisting of 0.5% CPF in water. Seven volunteers, aged 21–55 participated, with females taking a pregnancy test prior to participation to verify non-pregnant status and all volunteers deemed in good health from medical histories and physician's examination. All volunteers reviewed and gave informed consent prior to study initiation. The study design was approved by the internal Human Health Review Committee of The Dow Chemical Company and the Institutional Review Board for Approval of Research Involving Human Subjects at the University of Michigan Medical School.

The test was run twice, first with four volunteers in one apartment (Apartment 1), then three different volunteers in the second apartment (Apartment 2). After treatment, the seven adult volunteers, dressed in a T-shirt and shorts, conducted simple childlike movements (such as crawling, rolling or lying on their backs) on the respective carpets for 4h. The airborne concentration of CPF was measured on cassette filters backed by a Chromosorb tube 15 in. off the floor, where most of the activity took place. The time-weighted average (TWA) of air samples was 11.4mg/m^3 in the Apartment 1 and 5.53mg/m^3 in Apartment 2. The higher exposure metrics in Apartment 1 were attributed to rainy weather and high humidity on the day of the study retarding drying of the Empire*20 post application. Cassettes near each specific volunteer were measured and reported (Table 1). The parameters optimized from the data of Hotchkiss et al. (2013) described above were applied to the human model, and these TWA airborne concentrations input to estimate inhaled CPF from this study (Table 1).

After the exposure period, volunteer's hands were rinsed 3 times in 250ml of 0.008% dioctyl sodium sulfosuccinate soap to estimate dermal dose of CPF. The SA of the hands of an adult is | 4% of the total body SA and the SA of the body less the trunk (which was covered by the shorts and T-shirt) is | 66%. Assuming that the palms of the hands, the feet and lower limbs all receive about the same dose from the childlike activities and the back of the hands represent the lower dose of the rest of the body, the amount recovered on the hands was normalized to the total body SA not covered by clothing. This dermal dose was applied to the model, and the Kp previously optimized to fit the data of Nolan et al. (1984) was used to estimate total absorbed dose of CPF from the skin. Thus, each individual's exposure was simulated specifically to their body SA (as calculated from their BWT as described above), and their specific dermal loading, and based on the air sampling closest to them (Table 1).

Table 1. TWA Inhalaiton exposures were calcualted from dosimeters placed 15 in. off the surface of the carpet near the indivudals and hand washes were used to determine hand loading. Volunteer designations, BWT, TWA exposure, concentration of CPF on the hands and plasma cholinesterase activity were obtained from the report (Vaccaro et al., 1993).

Volunteer	Body wt (kg)	TWA inhalation exposure (mg/m^3)	CPF on hands (mg)	Extrapolated CPF dermal dose (mg)	Surface area exposed	Plasma ChE activity (% of pre-study)	
						30h	53h
Apartment 1							
P	55.8	12.5	1160	20300	10952	90	84
Q	55.8	3.1	825	14438	10952	53	49
R	57.7	17.7	2680	46900	11182	125	117
S	74.5	18.1	3330	58275	13004	148	132
Apartment 2							
T	90.7	12.2	630	11025	14689	158	154
U	88.5	5.2	386	6755	14448	162	155
V	49.9	9.9	267	4673	10192	70	66

Table 2. Dose metrics.

Volunteer	Extrapolated CPF dermal dose (mg)	Total CPF absorbed from skin (mg/cm^2)	Total CPF absorbed from both routes (mg)	Plasma ChE activity (% of pre-study)	
				30h	53h
Apartment 1					
P	19140	0.061	680.1	90	84
Q	13613	0.039	435.8	53	49
R	44220	0.133	1510	125	117
S	54945	0.163	2150	148	132
Apartment 2					
T	10395	0.038	565.3	158	154
U	6369	0.021	313.9	162	155
V	4406	0.019	200.2	70	66

Exposure and absorption calculated by the PBPK model for the simulated apartment exposures.

Results

The model code from the oral-route lifestage PBPK model described in Smith et al. (2014) was modified to include inhalation and dermal routes and parameterized based on known data or optimized, as described above. All model parameters are given in the Appendix, parameters specifically determined in this study are given in Table 2. Model code is available upon request.

Human oral and dermal model validation

Human oral and dermal exposure data from Nolan et al. (1984) were used to validate the model for these routes of exposure. In the study of Nolan et al, the subjects washed the exposure sites 12–24h after application, but the site was not occluded, so exposure length is uncertain. Using total urinary TCPy to estimate total dose absorbed, Nolan et al. calculated 1.3% absorption. This low level absorption is also consistent with that measured by Griffin et al. (1999), who estimated only 1% absorption based on total urinary metabolites. The model has an advantage over these estimates in that mass-balance is maintained for total absorption and any compound not appearing as a urinary metabolite will still be accounted for as CPF or minor metabolites. To determine a Kp value, exposure conditions were input as described above and all other model parameters were held constant. The fits of the model to the oral and dermal data from the study of Nolan et al. (1984) are shown in Figure 2. The Kp that resulted in the best fit to the plasma TCPy data was 4.65×10^{-4} cm/h. The urinary TCPy and plasma ChE inhibition were not used to calibrate the absorption rate and are shown to confirm the ability of the original model parameters to estimate the pharmacokinetics and pharmacodynamics of CPF exposures.

Overall, the multi-route PBPK/PD model provides very good predictions of the major biomarkers of CPF exposures in blood and urine via the oral and dermal exposure routes. Predictions of plasma cholinesterase inhibition are also seen, however as CPF is predicted to undergo a small amount of bioactivation in the skin compartment, this inhibition is slightly over-predicted. This dermal metabolism is consistent with what is known about P450 and esterase metabolism within the skin (Svensson, 2009), and since it is a large tissue should not be ignored. The dermal absorption model, optimized based on the most common biomarker, TCPy, also over-predicts circulating CPF, by ∼7 fold (Figure 2), and as a result downstream PD effects may also be over-estimated. Taken together, these two measures indicate some additional loss of CPF that is not accounted for in the model at this time. The fits to the plasma ChE inhibition data show that the loss of CPF is not to the active oxon.

Rat oral-route chlorpyrifos and chlorpyrifos oxon

In the original Timchalk et al. (2002b) study, male F344 rats were administered 0–100mg/kg CPF (po) in corn oil and the time course of cholinesterase inhibition in RBC and brain tissues determined in addition to plasma CPF concentrations (Figure 3). Marty et al. (2012) also orally administered 0–10mg/kg CPF or 0–0.5mg/kg CPF oxon to female CD rats and measured cholinesterase inhibition in RBC, plasma and brain over time following the highest dose or at peak (4 or 6h) for the lower doses (Figure 4). A comparison to fits of the data between the two studies is shown in Figure 5. The model fits high and low dose ChE inhibition data from Timchalk et al. (2002b) in brain and plasma. It also fits high and low dose plasma data from Marty et al. (2012), but under-predicts high dose brain inhibition.

Due to the lipophilicity of CPF and CPF oxon, rat dosing for both studies used a corn oil vehicle. Because of the vehicle, which alters absorption rates (Kim et al., 1990), and the use of gavage, which has also been shown to modify absorption (Kim et al., 1990; Marty et al., 2007), and the use of gavage, which has also been shown to modify absorption (Kaplan et al., 1997), an additional oral absorption parameter was added in the rat model but was unnecessary when simulating humans (Appendix). The model predictions of tissue cholinesterase activity from CPF acute oral exposures from Timchalk et al. (2002a) (Figure 3) and Marty et al. (2012) (Figure 4) match the empirical data quite well. In a similar fashion, the predicted levels of blood TCPy and tissue cholinesterase activity are also quite consistent with the acute CPF oxon results of Marty et al. (2012) (Figure 6).

Rat inhalation-route CPF

Previous acute exposure of female CD rats to saturated vapors of 35.3mg/m^3 CPF afforded no cholinesterase inhibition in RBC, plasma, lung or brain tissue (Hotchkiss et al., 2013). However, exposure of female CD rats to particulate aerosols of 3.7–53.5mg/m^3 CPF did afford measureable cholinesterase inhibition in one or more tissues. The PBPK/PD model for air exposures was therefore validated with the CPF particulate aerosol data.

Overall, the fit of the model to the inhalation data is quite good. The high circulating levels of TCPy are maintained longer thanwould be expected via an oral dose, and the model simulates this well (Figure 7). Likewise, cholinesterase in plasma, RBC and brain is all predicted within a factor of 3. For the lower doses, these fits are near unity.

Volunteer biomonitoring

The urinary elimination of TCPy was measured in seven volunteers after they performed child-like movements on carpets treated with CPF (Vaccaro et al., 1993). The airborne

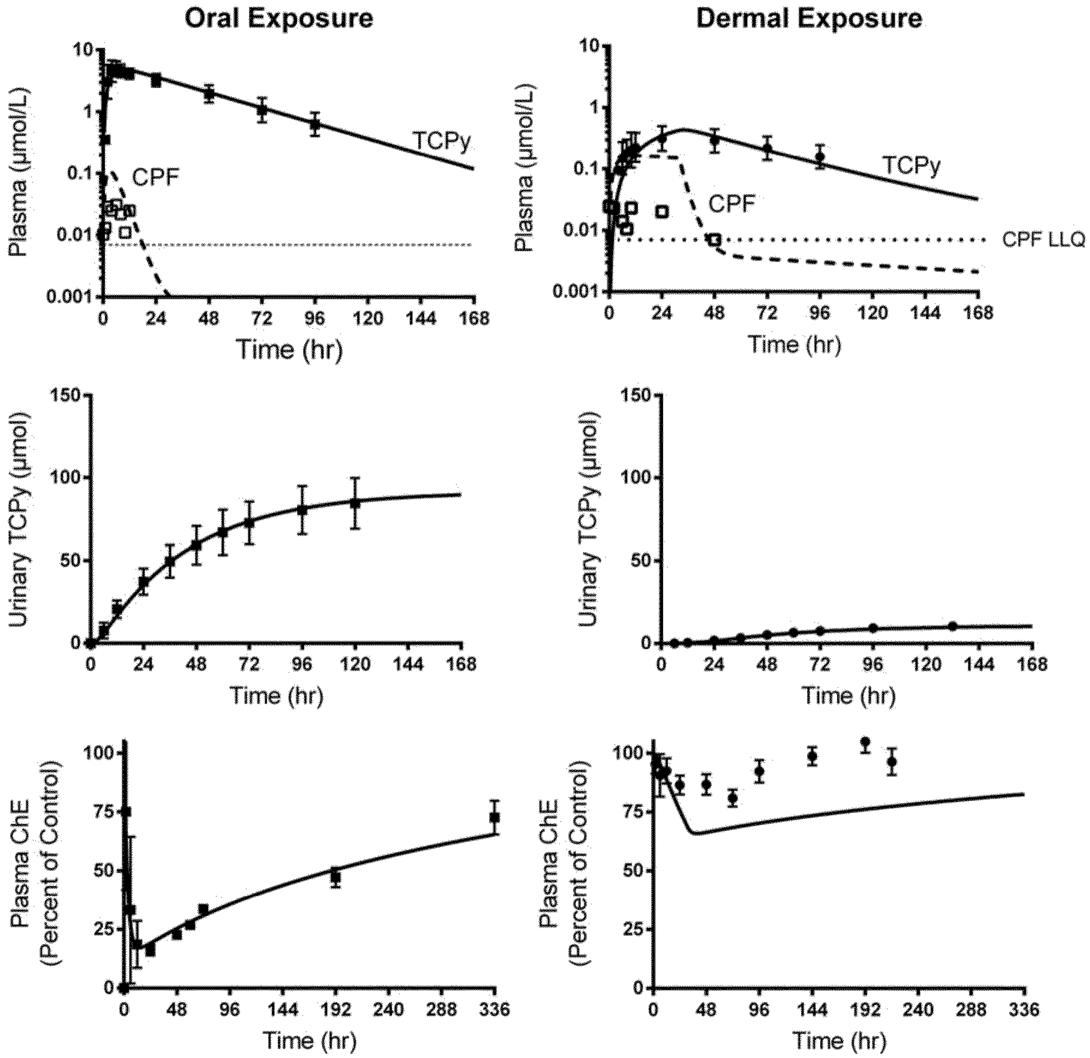

Figure 2. Pharmacokinetic and pharmacodynamic data from human volunteer exposures to chlorpyrifos via the oral and dermal routes. Lines are model simulations. Note the y-axis scales are different for pharmacokinetic data between the 2 routes, dermal route CPF and TCPy concentrations are much lower following the dermal exposures.

concentrations of CPF and the deposition of CPF on the hands of the volunteers were measured (Table 1). The measured air concentrations of CPF were likely particulate or aerosol exposures and were modeled as available for inhalation. The measured concentrations of CPF on the volunteers hands and the air monitoring showed greater than two fold the dermal exposures in the first apartment for all but one volunteer, and nearly two fold the airborne CPF concentration as well (Table 1). Each volunteer was individually modeled, accounting for specific BWTs and total dermal and inhalation exposures. The predicted urinary elimination from the individuals in Apartment 1 was consistent with actual results, with the average urinary levels of TCPy within 4% of measured (Figure 8). The fit to the urinary elimination data from the three individuals in the second apartment indicated a slight under-prediction. These three individuals had much lower exposures (dermal doses that averaged 40% of Apartment 1), yet the total measured urinary elimination was 643±293 mg in the volunteers from Apartment 1 and 516±100 mg in Apartment 2 (| 80%).

Possible sources of deviations from observed and predicted include other exposures to TCPy, variable loading of CPF on the hands over time, and non-linear clearance process that is not effectively accounted for by the model. All of the volunteers had background TCPy recovered in their urine prior to the exposures, and this background was subtracted out of the model exposures, but the pre-exposure TCPy may have indicated an external source of TCPy that was not accounted for. The lowest background TCPy was 13 and highest 52nmol (37mg/dl and 330mg/dl in volunteers R and Q, respectively). The hands were washed at the end of exposure only, and not sampled during exposure. The loading of CPF on the skin was assumed to be constant and described by that final wash concentration. Also, because the volunteers were adults, no hand to mouth (direct oral) exposures were expected.

Because of the low vapor pressure, internalized CPF in these subjects primarily comes from the dermal exposure, with very little stemming from inhalation (Figure 9; Table 2). Because the model calculates TSA based on BWT and height (Equation (3): Du Bois & Du Bois, 1916), the absorption

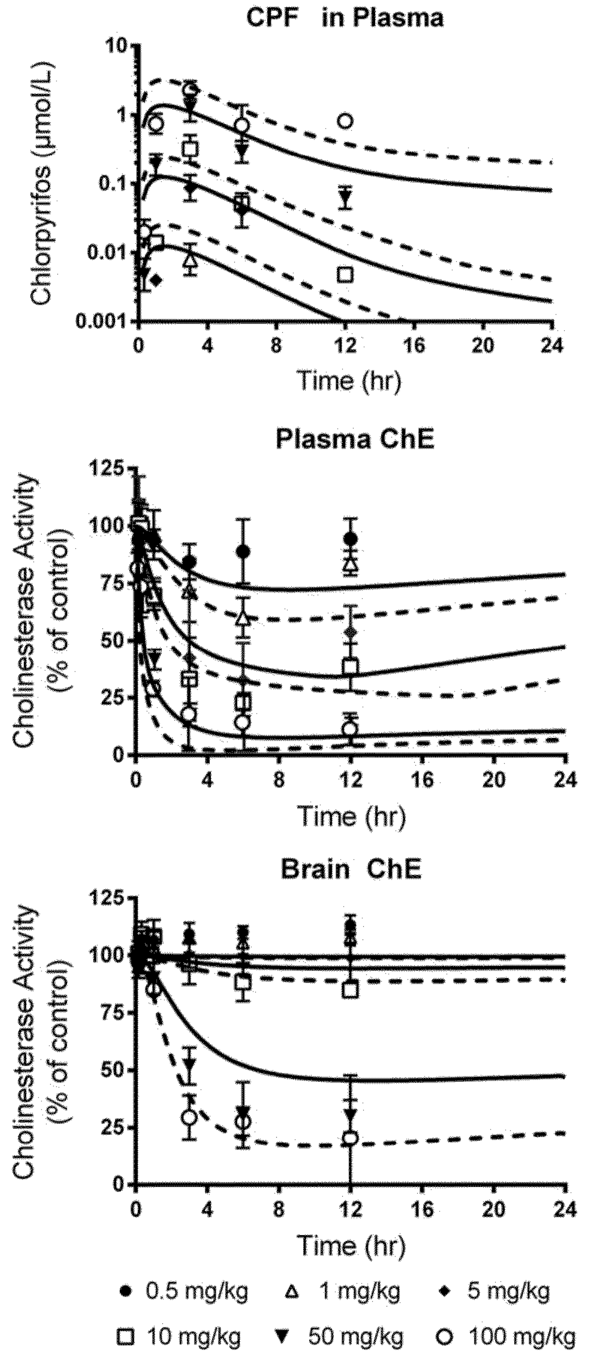

Figure 3. Pharmacokinetic and pharmacodynamic data from rats exposed to CPF via oral exposure (Timchalk et al., 2002a). Lines are model simulations. Data are mean±SD of n ¼4 animals.

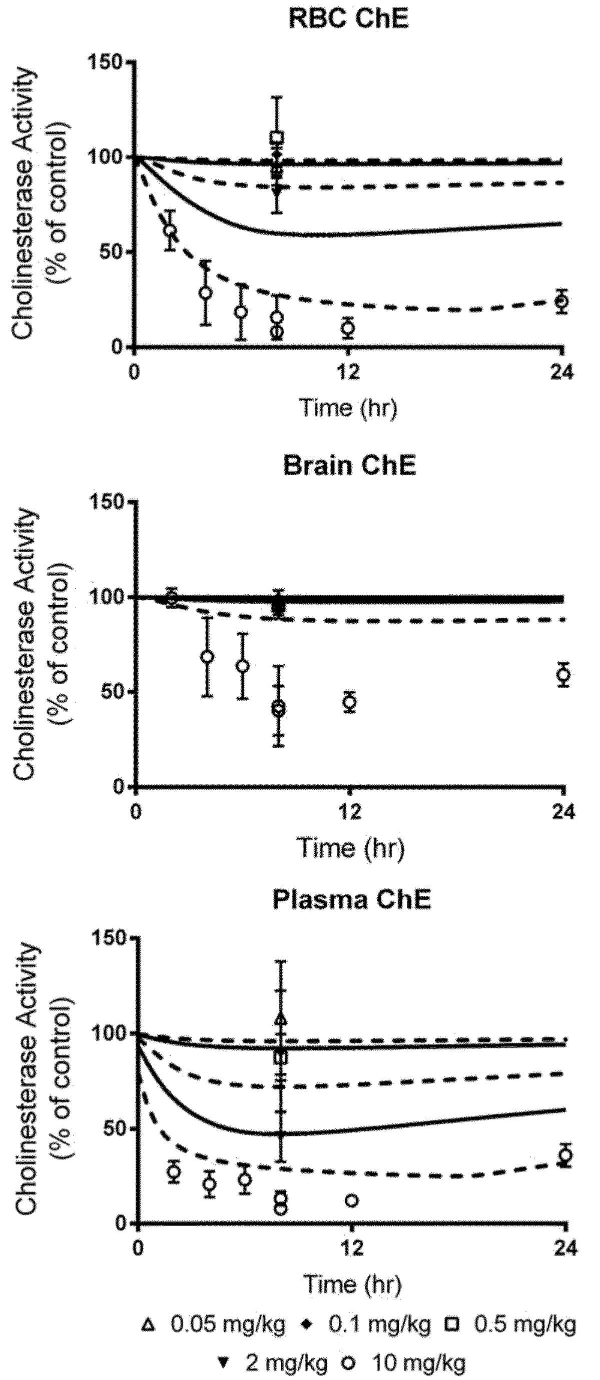

Figure 4. Cholinesterase inhibition data from rats exposed to CPF via oral exposures (Marty et al., 2012). Lines are model simulations. Data are mean±SD of n ¼8 animals.

predicted for each individual is based on their specific physiology, the difference in amount absorbed was due to each individual's SA. Cholinesterase activity following entry into the apartments was not related to internal or external CPF concentrations (Table 2).

Discussion

Although non-oral routes of exposure are often most important they are less commonly evaluated within pharmacokinetic/pharmacodynamic studies, thus necessitating route-to-route extrapolation (Poet & McDougal, 2002). The PBPK model, along with available human data to validate it, is an invaluable tool to achieve these extrapolations based on empirical data with minimal assumptions. In rats, although the acute oral toxicity of CPF is low (LD_{50} of 223mg/kg) (Stebbins, 1996), the acute dermal toxicity is even lower with an LD_{50} that is at least an order of magnitude higher

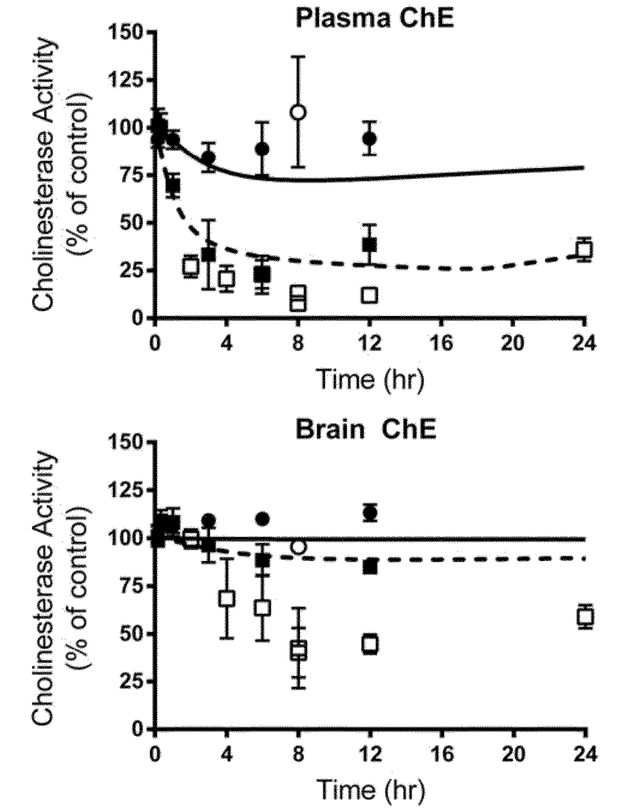

Figure 5. A direct comparison of fits to the data of Timchalk et al. (2002a) (filled symbols) and Marty et al. (2012) (open symbols) for the two doses in common – 0.5 and 10mg/kg. The BWTs in the two studies were slightly different, so the simulation lines are also slightly different. For clarity, only the fits to the Timchalk data are shown.

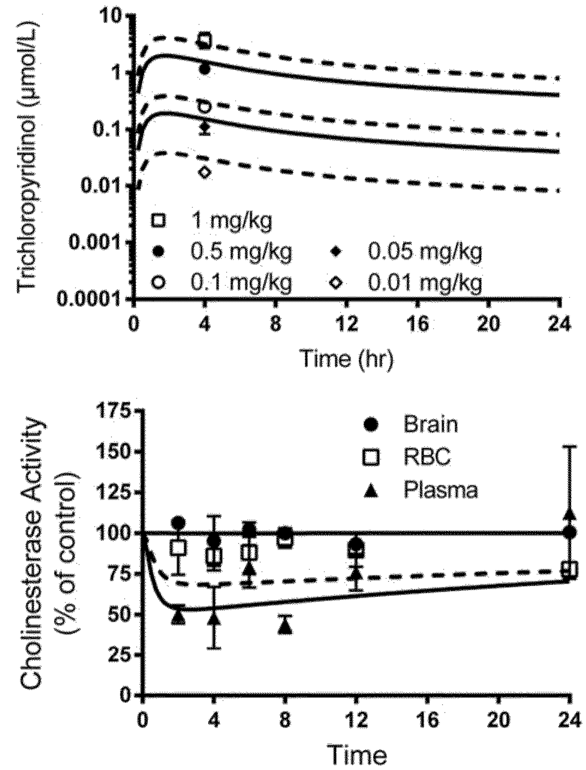

Figure 6. Mean blood TCPy levels in female rats sampled 4h after the last dose following daily gavage dosing with CPF oxon in corn oil and time-course of mean RBC, brain and plasma ChE inhibition in adult female rats following a gavage dosing with CPF oxon in corn oil vehicle at 0.5mg/kg (Marty et al., 2012).

(LD50 > 2000mg/kg) (Dow-MRID 44209101). Nolan et al. (1984) found approximately five-fold lower inhibition of plasma cholinesterase (ChE) activity, following application of a 5mg/kg BWT dose to the skin of human volunteers versus a 0.5mg/kg oral dose of CPF. These data, plus measurement of absorbed dose via urinary TCPy levels, indicate that approximately 1% of CPF is absorbed via the dermal route from the lower arm over 12h, versus nearly complete oral absorption.

The CPF lifestage model is somewhat unique in the total amount of available data available to parameterize the model (Smith et al., 2014). Metabolism and partitioning have been measured in vitro and extrapolated rather than optimized, and route-specific data are available in rats and humans. Nonetheless, some parameters have been optimized or calculated based on indirect evidence. Examples of this include the metabolic rates in non-hepatic tissues. Rates were measured in intestine (rats) and liver (rats and humans). The use of 2% of hepatic metabolism was estimated by fitting diaphragm cholinesterase inhibition (data not shown) and based on limited information about dermal and brain metabolism (Chambers & Chambers, 1989; Timchalk et al., 2012). One advantage to applying a constant percentage is that it facilitates species extrapolations based on species-specific measurements when they are available. The low level of metabolism in non-hepatic tissues is also supported by circulating levels of CPF, which are lower than would be predicted without extra-hepatic metabolism. Michaelis–Menten constants from the liver microsome in vitro studies were used in these simulations. Microsomes are manufactured micelles containing the CYP450s and lacking the natural structure or milieu of the cell, and these constants are usually optimized (Guengerich, 1994; Reddy et al., 2005). Michaelis–Menten constants were set equal to liver, again to avoid optimizations.

Any dose stemming from inhalation exposures will be low due to the very low vapor pressure of CPF. Metabolism in the upper and lower respiratory tract tissues (lung, nasal and conducting airway tissues) was set equal to that measured in the liver, consistent with other studies showing equal, or even higher P450 metabolism in nasal tissues (Dahl & Hadley, 1991; Sarkar, 1992). The high rate of metabolism and 100% bioavailability of inhaled CPF are highly conservative, but do fit the TCPy plasma concentration data and the plasma cholinesterase inhibition is likewise successfully simulated. Even with the assumption of 100% absorbed, much of the dose of aerosol is expected to be deposited in the nasal airways and be absorbed following clearance to the GI tract. Lipophilic chemicals will deposit in this region and have been shown to be well absorbed and metabolized (Corbo et al., 1989; Gerde & Scott, 2001; Song et al., 2004).

The major, non-oral route of exposure for CPF is likely to be via absorption through the skin. This model has been optimized from the data of Nolan et al. (1984). The optimized Kp was based on the assumption that the non-occluded exposures described in Nolan et al. (1984) were

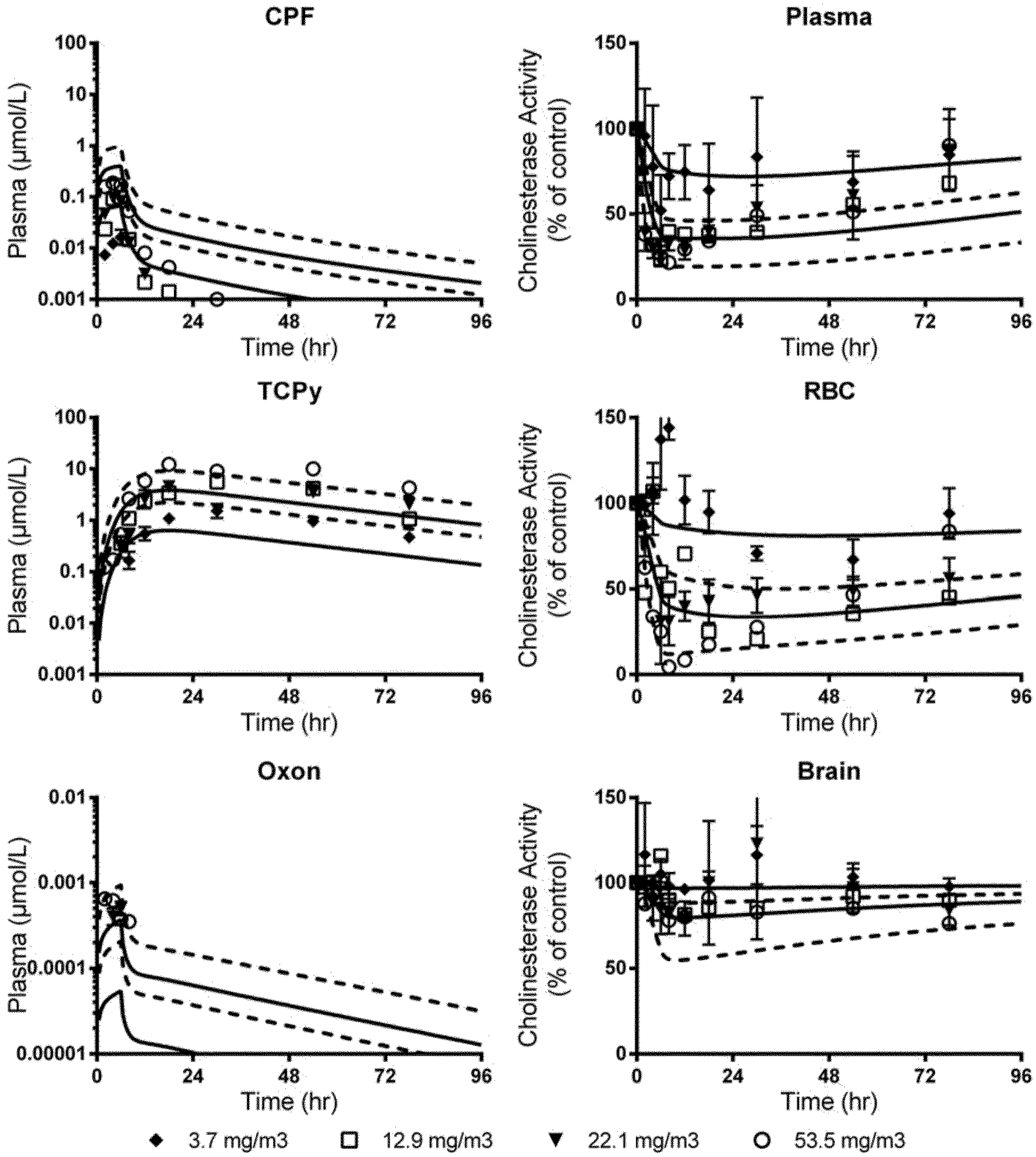

Figure 7. Mean CPF, TCPy and oxon pharmacokinetics in plasma and plasma, RBC and brain ChE inhibition following an inhalation exposure (Hotchkiss et al., 2013).

maintained on the skin for 24h and not rubbed or washed off. Historically, it was assumed that only ~1.5% of the dose was available to be absorbed (Timchalk et al., 2002b). The Kp optimized using this assumption is ~5.5×10^{-5}, consistent with the previous predictions. Data from exposure to volunteers after carpet treatment with a CPF solution validate this Kp in a simulated real-world scenario.

This model has many potential uses for biomonitoring, including the determination of biomonitoring equivalents (Becker et al., 2012). To compare biomonitoring endpoints from different routes, potential internal concentrations of CPF and TCPy were compared after an equivalent absorbed CPF dose from an oral or dermal route. Oral CPF is considered to be 100% absorbed, so an oral dose of 3mg/kg was compared with a dermal dose of 180mg/kg (76kg individual over 40% of the TSA, equivalent to the upper extremities, for 6h), which was predicted to result in an absorbed dose of 3.04mg/kg. Because non-oral routes, such as dermal, circumvent first pass metabolism to both the active oxon and to TCPy, the plasma CPF is predicted to have nearly 50 fold higher AUC following a dermal exposure (Figure 10), yet RBC ChE inhibition is less than 1% from both routes. Because the entire dose is converted to TCPy, peak plasma TCPy and urinary elimination are similar, regardless of route, but the peak is delayed following a dermal dose. Thus, if CPF is used as a biomarker, and the route of exposure is not taken into account external exposure may be misinterpreted, and TCPy might be more accurate of total exposure. However, TCPy used as a biomarker can also be confounded by exposures to other chemicals or to TCPy itself.

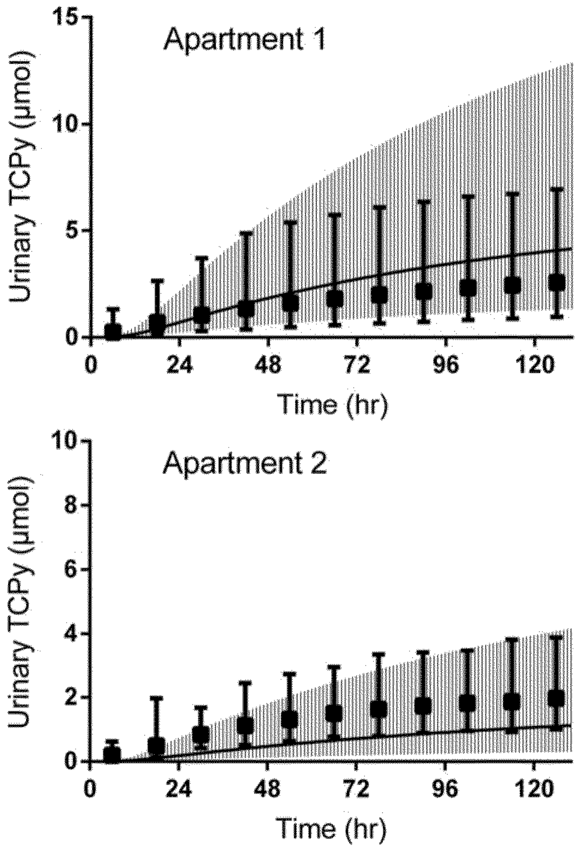

Figure 8. Urinary elimination in seven volunteers following re-entry into an apartment after carpet treatment with a CPF mixture. The individuals in Apartment 1 (n¼4), had a higher dermal load of CPF than those in Apartment 2. Individual data are mean ± SD excreted TCPy, the line and shaded area are the mean ± SD of the model runs.

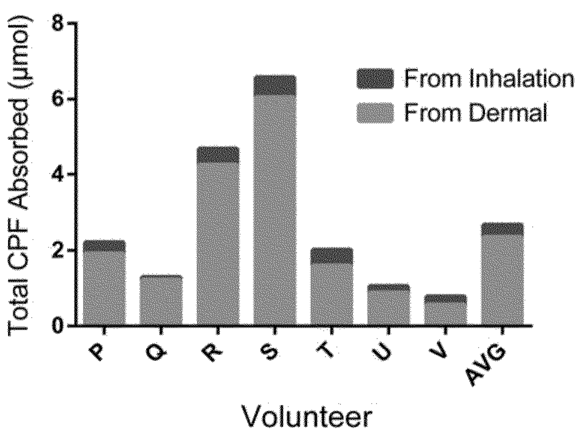

Figure 9. The volunteers were exposed to CPF via both inhalation and dermal routes. The predicted total CPF uptake from the two routes shows that most of the absorbed CPF comes from the dermal dose.

Overall, the model fits to the multi-route data are very good. Table 3 shows a summary of species- and route-specific data sets that are available and have been used to comprehensively validate the PBPK/PD model. The oral route has the most data for model validation in both species. Using a parallelogram approach, it can be assumed that brain and lung

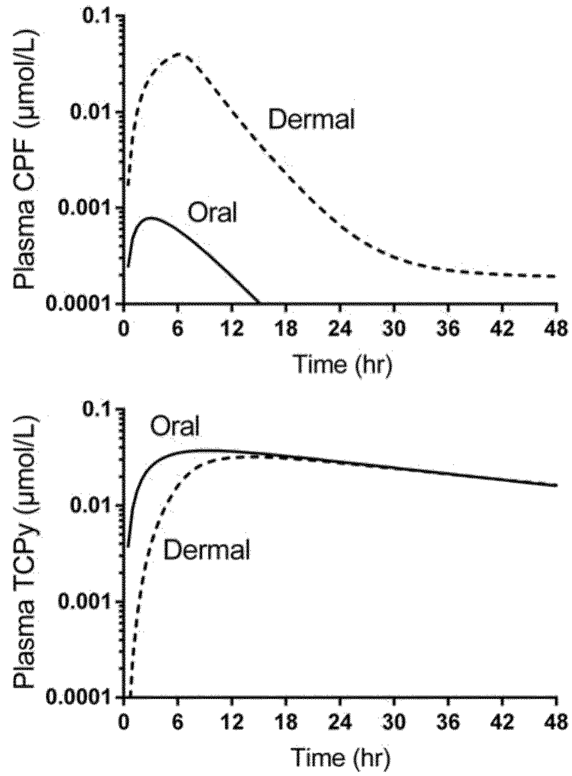

Figure 10. The model was used to predict plasma indicators of CPF exposure following an oral or a dermal exposure. Plasma levels of TCPy are consistent between routes, but, because of bypassing first pass metabolism, parent CPF is predicted to be higher following a dermal exposure.

Table 3. Qualitative assessment of model validation.

	Pharmacokinetic biomarkers				ChE biomarkers			
	Blood CPF	Blood oxon	Blood TCPy	Urine TCPy	Plasma	RBC	Diaphragm/ lung	Brain
Route								
Oral								
Rat	x	x	x	x	x	x	x	x
Human	x	x	x	x	x	x		
Inhalation								
Rat	x	x	x	x	x	x	x	x
Human								
Dermal								
Rat					x	x		x
Human	x		x	x	x	x		

The x symbols represent data sets available to validate the PBPK/PD model.

ChE inhibition are likely predictive from human simulations via an oral route. The inhalation route is well-validated in rats and pharmacokinetic metrics as they relate toTCPy are likely predictive in humans, but there is less confidence in model fits to brain ChE inhibition in humans, as this parameter has not been measured from any low exposure scenarios in human. The dermal route, on the other hand, has been validated in humans more so than in rats, and shows excellent fits, especially for the TCPy biomarker and ChE inhibition. CPF blood levels are slightly over-predicted, and as a result, downstream PD effects may also be over-estimated.

This model has been well validated for the prediction of PK biomarkers and ChE inhibition in humans exposed to CPF via oral, inhalation and dermal routes. It will therefore be an important tool to conduct species- and route-extrapolations and has potential applications in biomonitoring and exposure assessment.

Declaration of interest

The authors report no conflicts of interest. The authors alone are responsible for the content and writing of this article.

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Appendix. Rat and Human Model Parameters

Parameter	Name	Rat value	Source	Human value	Source
Blood flow (L/h/kg tissue)					
Brain	QBC	66	Brown et al. (1997)	30.6	Price et al. (2011)
Liver	QHC	78.6	Brown et al. (1997)	50.4	Price et al. (2011)
Fat	QFC	19.8	Brown et al. (1997)	1.45	Luecke et al. (2007) and Price et al. (2011)
Rapidly perfused	QRC	300	Luecke et al. (2007)	61.8	Adrenal/spleen mean: Price et al. (2011)
Slowly perfused	QSC	4.8	Bone marrow, Luecke et al. (2007)	1.8	Bone marrow: Price et al. (2011)
Diaphragm	QDC	90	Gearhart et al. (1994)	85.2	Luecke et al. (2007)
Partition coefficients (tissue:blood)					
CPF					
Brain	PBC	16.5	Lowe et al. (2009)	16.5	Lowe et al. (2009)
Liver	PHC	12.8	Lowe et al. (2009)	12.8	Lowe et al. (2009)
Fat	PFC	250	Lowe et al. (2009)	250	Lowe et al. (2009)

(continued)

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Table Continued

Parameter	Name	Rat value	Source	Human value	Source
Rapidly perfused	PRC	16.5	Lowe et al. (2009); rapid ¼ brain	16.5	Lowe et al. (2009); rapid ¼ brain
Slowly perfused	PSC	3.85	Lowe et al. (2009)	3.85	Lowe et al. (2009)
Diaphragm	PDC	3.85	Lowe et al. (2009)	3.85	Lowe et al. (2009)
Lung	PLU	16.5	¼brain	16.5	¼brain
Skin	PSKL	200	combination of partitioning and blood flow, optimized	200	combination of partitioning and blood flow, optimized
CPF-oxon					
Brain	PBO	5.6	Lowe et al. (2009)	5.6	Lowe et al. (2009)
Liver	PHO	4.5	Lowe et al. (2009)	4.5	Lowe et al. (2009)
Fat	PFO	75	Lowe et al. (2009)	75	Lowe et al. (2009)
Rapidly perfused	PRO	5.6	¼brain	5.6	¼brain
Slowly perfused	PSO	1.8	Lowe et al. (2009)	1.8	Lowe et al. (2009)
Diaphragm	PDO	1.8	Lowe et al. (2009)	1.8	Lowe et al. (2009)
Lung	PLU	5.6	¼brain	5.6	¼brain
Skin*	PSKIO	200	Equal to CPF	200	Equal to CPF
Hepatic dearylation					
V_{max} (mmol/h/kg)	VMHCP	1762	Poet et al. (2003)	1360	Smith et al. (2011) and Wilson et al. (2003)
K_m (mM)	KMHP	4.1	Poet et al. (2003)	21	Smith et al. (2011) and Poulin & Haddad (2011)
Hepatic desulfuration					
V_{max} (mmol/h/kg)	VMHHCO	413	Poet et al. (2003)	630	Smith et al. (2011) and Wilson et al. (2003)
K_m (mM)	KMHHCO	10.6	Poet et al. (2003)	33.2	Smith et al. (2011) and Poulin & Haddad (2011)
Hepatic CPF-oxon hydrolysis					
V_{max} (mmol/h/kg)	VML	1.90E+06	Poet et al. (2003)	1.29×10^5	Smith et al. (2011) and Wilson et al. (2003)
K_m (mM)	KMLST	345	Poet et al. (2003)	192	Smith et al. (2011) and Poulin & Haddad (2011)
Blood CPF-oxon hydrolysis					
V_{max} (mmol/h/kg)	VMBL	Logistic fit	Smith et al. (2011)	Logistic fit	Smith et al. (2011)
K_m (mM)	KMBLST	192	Smith et al. (2011)	192	Smith et al. (2011)
Intestinal dearylation					
V_{max} (mmol/h/kg)	VINTTC	68	Poet et al. (2003)	53	Poet et al. (2003)
K_m (mM)	KMINTC	55	Poet et al. (2003)	21	Measured in liver Smith et al. (2011) and Poulin & Haddad (2011)
Intestinal desulfuration					
V_{max} (mmol/h/kg)	VINTOC	18	Poet et al. (2003)	82	Poet et al. (2003)
K_m (mM)	KMINTO	8.1	Poet et al. (2003)	192	Measured in liver Smith et al. (2011) and Poulin & Haddad (2011)
Intestinal CPF-oxon hydrolysis					
V_{max} (mmol/hr/kg)	VINTOXC	1256	Poet et al. (2003)	28	Poet et al. (2003)
K_m (mM)	KMINTOX	328	Poet et al. (2003)	33.2	Measured in liver Smith et al. (2011) and Poulin & Haddad (2011)
Brain dearylation					
V_{max} (mmol/h/kg)	VMCBCP	35.2	2% of Hepatic	27.2	2% of Hepatic
K_m (mM)	KMBCP	4.1	Hepatic	21	Hepatic
Brain desulfuration					
V_{max} (mmol/h/kg)	VMCBCO	8.26	2% of Hepatic	12.6	2% of Hepatic
K_m (mM)	KMBCO	10.6	Hepatic	33.2	Hepatic
Pulmonary dearylation					
V_{max} (mmol/h/kg)	VMAXTLUC	1762	Hepatic	1360	Hepatic
K_m (mM)	KMTLU	4.1	Hepatic	21	Hepatic
Pulmonary desulfuration					
V_{max} (mmol/h/kg)	VMAXOLUC	413	Hepatic	630	Hepatic
K_m (mM)	KMTLU	10.6	Hepatic	33.2	Hepatic
Dermal dearylation					
V_{max} (mmol/h/kg)	VMCDERMCP	35.2	2% of Hepatic	27.2	2% of Hepatic
K_m (mM)	KMDERMCP	4.1	Hepatic	21	Hepatic
Dermal desulfuration					
V_{max} (mmol/h/kg)	VMCDERMCO	8.26	2% of Hepatic	12.6	2% of Hepatic
K_m (mM)	KMDERMCO	10.6	Hepatic	33.2	Hepatic
Diaphragm dearylation					
V_{max} (mmol/h/kg)	VMCDPCP	35.2	2% of Hepatic	27.2	2% of Hepatic
K_m (mM)	KMDPCP	4.1	Hepatic	21	Hepatic

(continued)

Table Continued

Parameter	Name	Rat value	Source	Human value	Source
Diaphragm desulfuration					
V_{max} (mmol/h/kg)	VMCDPCO	8.26	2% of Hepatic	12.6	2% of Hepatic
K_m (mM)	KMDPCO	10.6	Hepatic	33.2	Hepatic
Transfer rates (/h)					
CPF stomach to liver	KAS	0.1	Fit to Timchalk et al. (2002b)	NA	
CPF stomach to intestine	KSI	0.25	Fit to Timchalk et al. (2002b)	0.31/0.086	Fit to Nolan et al. (1984)/ Timchalk et al. (2002a)
Intestinal absorption to liver					
CPF	KAI	0.005	Fit to Timchalk et al. (2002b)	3.1	Fit to Nolan et al. (1984)
CPF-oxon	KOS	2	Fit to Marty et al. (2012)	3.9	Fit to rat data Marty et al. (2012)
TCPy	KIHP	8.5	Fit to rat data Timchalk et al. (2007) and Busby-Hjerpe et al. (2010)	8.5	Fit to rat data Timchalk et al. (2007) and Busby-Hjerpe et al. (2010)
Dermal absorption rate	KPL	5.5e-05	Fit to Nolan et al. (1984)	5.5e-05	Fit to Nolan et al. (1984)
Plasma protein binding (%)					
CPF	FBC	99	Lowe et al. (2009)	99	Lowe et al. (2009)
Oxon	FBO	99	Lowe et al. (2009)	99	Lowe et al. (2009)
TCPy compartmental model					
K_e (/h)	KE	0.26	fit to Timchalk et al. (2002b)	0.024	Nolan et al. (1984)
Enzyme activity (mmol/kg/h)					
AChE					
Brain	BACHE	4.4 └ 10^5	Maxwell et al. (1987)	4.4 └ 10^5	Maxwell et al. (1987)
Plasma	BLACHE	2.33 └ 10^4	Timchalk et al. (2002b)	NA	Timchalk et al. (2002a)
Liver	HACHE	1.02 └ 10^4	Maxwell et al. (1987)	1.02 └ 10^4	Maxwell et al. (1987)
RBCs	RBCHE	3.39 └ 10^4	Zheng et al. (2000)	4.27 └ 10^5	Albers et al. (2010)
Diaphram	DACHE	7.74 └ 10^4	Maxwell et al. (1987)	7.74 └ 10^4	Maxwell et al. (1987)
Pulmonary	LUACHE	2.28 └ 10^4	Maxwell et al. (1987)	2.28 └ 10^4	Maxwell et al. (1987)
BuChE					
Brain	BBUCE	4.68 └ 10^4	Maxwell et al. (1987)	4.68 └ 10^4	Maxwell et al. (1987)
Plasma	BLBUCE	7.85 └ 103	Carr et al. (2001)	2.63 └ 10^5	Sidell & Kaminskis (1975)
Liver	HBUCE	3.0 └ 10^4	Maxwell et al. (1987)	3.0 └ 10^4	Maxwell et al. (1987)
Diaphram	DBUCE	2.64 └ 10^4	Maxwell et al. (1987)	2.64 └ 10^4	Maxwell et al. (1987)
Pulmonary	LUBCE	8.64 └ 10^4	Maxwell et al. (1987)	8.64 └ 10^4	Maxwell et al. (1987)
Carboxylesterase					
Brain	BECE	2.88 └ 10^5	Hojring & Svensmark (1976)	2.88 └ 10^5	Hojring & Svensmark (1976)
Plasma	PLOCE	8.4 └ 104	Li et al. (2005)	NA	Li et al. (2005)
Liver	HECE	1.94 └ 10^6	Karanth & Pope (2000)	1.27 └ 10^6	Pope et al. (2005)
Diaphram	DECE	3.18 └ 10^5	Maxwell et al. (1987)	3.18 └ 10^5	Maxwell et al. (1987)
Pulmonary	LUECE	1.4 └ 10^6	Maxwell et al. (1987)	1.4 └ 10^6	Maxwell et al. (1987)
Degradation rates (/h)*					
AChE	KD └ CE	0.003	Fit to Timchalk et al. (2002b)	0.01	Timchalk et al. (2002a) and Gearhart et al. (1994)
BuChE	KD └ BE	0.01	Timchalk et al. (2002b)	0.0024	Fit to Nolan et al. (1984)
Carboxylesterase	KD └ CR	0.001	Fit to Timchalk et al. (2002b)	0.001	Timchalk et al. (2002a).
Brain	KDBCR	7.54 └ $10^{┘4}$	Timchalk et al. (2002b)	7.54 └ $10^{┘4}$	Timchalk et al. (2002a)
Enzyme reactivation rate (/h)					
Acetyl	KR └ CE	0.014	Carr & Chambers (1996) and Timchalk et al. (2002b)	0.014	Carr & Chambers (1996) and Timchalk et al. (2002a)
Butyryl	KR └ BE	0.014	Carr & Chambers (1996) and Timchalk et al. (2002b)	0.0014	Carr & Chambers (1996) and Timchalk et al. (2002a)
Carboxyl	KR └ CR	0.014	Carr & Chambers (1996) and Timchalk et al. (2002b)	0.014	Carr & Chambers (1996) and Timchalk et al. (2002a)
Enzyme aging rate (/h)	KA └ BE/CE/CR	0.0113	Carr & Chambers (1996) and Timchalk et al. (2002b)	0.0113	Carr & Chambers (1996) and Timchalk et al. (2002a)
Enzyme turnover rate (/h)					
Acetyl	TRCE	1.17 └ 10^7	Maxwell et al. (1987)	1.17 └ 10^7	Maxwell et al. (1987)
Butyryl	TRBE	3.66 └ 10^6	Maxwell et al. (1987)	3.66 └ 10^6	Maxwell et al. (1987)
Carboxyl	TRCR	1.086 └ 10^5	Maxwell et al. (1987)	1.086 └ 10^5	Maxwell et al. (1987)
Bimolecular inhibition rate (mM/h)					
Acetyl	KI └ CE	220	Kousba et al. (2004) and Kousba et al. (2007)	220	Kousba et al. (2004) and Kousba et al. (2007)
RBCs	KIRBCE	500	Timchalk et al. (2002b)	100	Timchalk et al. (2002a)
Butyryl	KI └ BE	2000	Timchalk et al. (2002b)	2000	Timchalk et al. (2002a)
Carboxylesterase	KI └ CR	20	Timchalk et al. (2002b)	20	Timchalk et al. (2002a)

*"└" denotes specific tissues, in general: H, liver; B, brain; BL, blood; D, diaphragm; LU, lung.

To: Wolf, Joel[Wolf.Joel@epa.gov]
From: Oliver, George (GR)
Sent: Thur 5/28/2015 1:27:08 PM
Subject: RE: List of current uses for chlorpyrifos DAS to discuss whether to support further with EPA

.....
;;;;;
Joel, I want to thank you for the dialogue. I think in our effort to be all inclusive, we cut too finely for what EPA wants- to us, it made sense because we were so close to it. I am working now to try and define more broadly – so I appreciate your comments since that is really the next step I was hoping for – to discuss with EPA in the way that best works for you also.

George

From: Wolf, Joel [mailto:Wolf.Joel@epa.gov]
Sent: Thursday, May 28, 2015 8:30 AM
To: Oliver, George (GR)
Cc: Myers, Tom
Subject: RE: List of current uses for chlorpyrifos DAS to discuss whether to support further with EPA

Thanks for the below George. I look forward to our continued discussions.

Best, Joel

From: Oliver, George (GR) [mailto:groliver@dow.com]
Sent: Thursday, May 28, 2015 7:19 AM
To: Wolf, Joel
Cc: Myers, Tom
Subject: RE: List of current uses for chlorpyrifos DAS to discuss whether to support further with EPA

Joel,

I sincerely apologize for any confusion created by our proposal. The way the EPA assessment was conducted was very challenging to understand and deconstruct to fully understand what was failing the assessment and why. That is what took a great deal of time. Then we were working from the assessment scenarios that were assessed to evaluate the uses and come up with the list. I can assure you we have been working diligently on this and worked to provide the Agency with at least the initial response on uses as soon as the comment period closed.

Based on our conversations I have a good understanding of what the Agency is asking and we are working as quickly as we can to clarify. While as we note in our response comments to the docket, we do not necessarily agree with aspects of the Agency's setting of endpoints and then assessments, we continue to be willing to work to remove some uses that did not pass the current assessment.

With regards to your questions and I will be able to provide a more complete understanding and explanation next week:

∀ Our evaluation of uses was based on specific use scenarios and we have proposed not supporting specific uses rather than the entire crop. In many of these, according to our evaluation, some of the rates or methods of application do pass with what is currently on the label for PPE/EC and would be very willing to work with EPA to understand if your assessment shows the same. In many of the uses we are proposing, however, it will be the entire method of application – but I am working to clarify that. So for example, while we might not be proposing to offer ground boom application since it is an important use and we believe passes, we would be offering all rates of application for aerial.

Again, I apologize for any confusion, and want to stress that we have been working diligently to address the concerns and appreciate the Agency's cooperation on a very complex assessment.

Best regards

George

George R. Oliver, PhD
US Regulatory Leader
Dow AgroSciences
9330 Zionsville Rd
Indianapolis, IN 46027

groliver@dow.com
(317) 337.4923

From: Wolf, Joel [mailto:Wolf.Joel@epa.gov]
Sent: Wednesday, May 27, 2015 5:15 PM
To: Oliver, George (GR)
Cc: Myers, Tom
Subject: RE: List of current uses for chlorpyrifos DAS to discuss whether to support further with EPA

Hi George,

I look forward to the additional clarification based on our phone call this morning. Until additional clarification is forthcoming, my current understanding for the proposal that DAS has submitted is the following

1. The proposal does not include a single crop that DAS would cease to support in its entirety, and

2. DAS is only proposing to cease to support the specific rate indicated, nothing more or nothing less

a. E.g. if DAS has proposed that it will no longer support a 2 lb rate on strawberries in the liquid formulation applied aerially or chemigation, DAS would still support a 1.9 lb rate on strawberries in the liquid formulation applied aerially or chemigation or if there was a granular application at 2 lbs or even 3 lbs that could be used aerially or via chemigation DAS would still support this. (this example is made up, but meant to illustrate a point)

If I am misunderstanding the proposal, please let me know. I must confess that it is hard to believe that DAS' proposal took 5 months and that it could not be presented in a clearer manner. I'm hoping that the additional clarification you provide at least by the webinar next week if not sooner provides greater clarity.

I will send you some times tomorrow for late next week that would work for us regarding a webinar on DAS' proposal.

Thanks, Joel

From: Oliver, George (GR) [mailto:groliver@dow.com]
Sent: Friday, May 22, 2015 9:17 AM
To: Wolf, Joel
Cc: Myers, Tom
Subject: List of current uses for chlorpyrifos DAS to discuss whether to support further with EPA

Joel,

As we indicated during our meeting in April, DAS has been working to identify those uses that we would be willing to discuss with the Agency a commitment to withdraw support. We have made a good faith effort to identify those and attached is a list of over 60 specific uses that fall into this group. We appreciate the Agency's patience in DAS providing this list, but we wanted to be sure to let the comment period end and also to talk with stakeholders.

A few important points regarding the list:

∀ These are the uses DAS is proposing and we are not speaking for other registrants. We will notify Adama, Cheminova and Gharda of the submission of this list so they can then work with the Agency as appropriate.

∀ The list is of specific, individual uses on a crop or commodity. There may be other uses on that crop that are not included. So the list is use-specific rather than crop-general

After you have had a chance to initially review the list, we would like to discuss the process going forward with you further. Timing for any announcement by the Agency and then actual implementation are important considerations we would like to discuss. We can also explain the specific uses in more detail if you have any questions. Our proposal would be to hold actual implementation until the time any actions resulting from the EFED assessment are also addressed. We are willing to officially commit to any withdraw sooner and even make the information public to meet Agency needs and interests, but we can clearly delineate that in our discussions.

Since I would hope that a few key DAS people can participate, a conference call or webex meeting is probably more practical than travel into DC at least for this meeting. If you can give me an idea of when EPA would be able to discuss the process moving forward, I can work with you to set up some time.

We appreciate the Agency continuing to work with DAS to resolve the issues raised in the RHHA.

Best regards, and hope you have a great holiday weekend ahead.

George

To: Laura Phelps[Laura.Phelps@adama.com]
Cc: Wolf, Joel[Wolf.Joel@epa.gov]
From: O'Toole, Susan J - APHIS
Sent: Tue 6/23/2015 6:50:10 PM
Subject: RE: Chlopyrifos and Imported Fire Ant Program
2013 IFA nursery doc final 8-5-13.pdf

....
,,,,,,,,,,
Hi Laura,

Our lead scientist is out of the office and I would like to speak with her before we give a definitive answer to EPA's question.

However, I would like to share with you and Mr. Wolf, a copy of the APHIS PPQ Imported Fire Ant Treatment Manual, which describes all Federally-required IFA treatments in detail. Perhaps it will be of help to EPA as they conduct their assessments . . . as you will see, the use sites cover a variety of nursery stock materials that are restricted from movement out of the IFA-quarantined areas until appropriate treatments are made.

Hope this helps.

Susan O'Toole

National Pesticide Coordinator

Plant Protection and Quarantine

Animal and Plant Health Inspection Service

United States Department of Agriculture

4700 River Road, Unit 134

Riverdale, MD 20737

301-851-2243

sotoole@aphis.usda.gov

From: Laura Phelps [mailto:Laura.Phelps@adama.com]
Sent: Monday, June 22, 2015 4:52 PM
To: O'Toole, Susan J - APHIS
Subject: FW: Chlopyrifos and Imported Fire Ant Program

See Joel's note- is there someone you might know to call who would have the answer?

From: Wolf, Joel [mailto:Wolf.Joel@epa.gov]

Sent: Monday, June 22, 2015 4:50 PM
To: Laura Phelps
Subject: RE: Chlopyrifos and Imported Fire Ant Program

Hi Laura,

I did have one question. Do you know what the lowest effective application rate is, in your opinion, for the fire ant use?

Thanks, Joel

From: Laura Phelps [mailto:Laura.Phelps@adama.com]
Sent: Monday, June 22, 2015 2:32 PM
To: Wolf, Joel
Subject: FW: Chlopyrifos and Imported Fire Ant Program

Hi Joel,

Please see the letter below from Susan at USDA. ADAMA would like to be sure to do what we can to protect this fire ant use. Is there anything I need to supply at this time to help in the review?

Thank you,

Laaura

Laura Phelps
Product Registration Manager
D +919-256-9329 | M +919-353-2439
E laura.phelps@us.adama.com

ADAMA

www.adama.com

From: O'Toole, Susan J - APHIS [mailto:Susan.J.O'Toole@aphis.usda.gov]
Sent: Monday, June 22, 2015 12:57 PM
To: Laura Phelps
Cc: Defeo, Valerie F - APHIS
Subject: Chlopyrifos and Imported Fire Ant Program

Hi Laura,

Thank you for taking the time to speak with me at noon today and for letting me know that ADAMA is willing to support the IFA uses currently listed on ADAMA and associated distributor labels.

As I mentioned over the phone, PPQ's Imported Fire Ant (IFA) Program desires to retain all uses of chlorpyrifos currently contained on all labels by ADAMA or their distributors.

Of great concern is its potential loss of use as a drench to treat balled and burlapped nursery stock, because there are no alternative chemicals registered for that use.

Also of concern is the potential loss of use of chlorpyrifos to treat containerized nursery stock. This concern is due to the fact that any slow-down in the movement of IFA-regulated articles out of a nursery greatly impacts the nursery's ability to stay competitive. Due to the rapid exhibition of efficacy of chlorpyrifos, Federal regulations permit chlorpyrifos-treated containerized nursery stock to move out of quarantine within 24 hours of being treated. However, regulations mandate that containerized nursery stock treated with alternative products, which days take days to exhibit adequate efficacy, may not move out of quarantine for a number of days after they have been treated.

Attached please find a list of products whose labels permit appropriate uses of chlorpyrifos to target fire ant on containerized and balled-and-burlapped nursery stock. There may be other labels in existence – we are not completely sure of all the distributors' labels available at this point.

I understand from you the following:

1. Dow is the lead negotiator with EPA on the Registration Review process;

2. Dow has removed all IFA uses of chlopyrifos from their labels and does not intend to get involved with IFA uses;

3. That the EFED evaluation, which has not yet been completed, may address IFA uses, and that the HED review is completed.

It was nice speaking with you today. Kindly keep us in the loop if you hear anything about potential problems in retaining IFA uses.

Warm regards,

Susan O'Toole

National Pesticide Coordinator

Plant Protection and Quarantine

Animal and Plant Health Inspection Service

United States Department of Agriculture

4700 River Road, Unit 134

Riverdale, MD 20737

301-851-2243

sotoole@aphis.usda.gov

To: Wolf, Joel[Wolf.Joel@epa.gov]; Laura Phelps[Laura.Phelps@adama.com]
From: O'Toole, Susan J - APHIS
Sent: Thur 7/9/2015 8:53:41 PM
Subject: RE: Chlopyrifos and Imported Fire Ant Program

....
;;;;;;;;;;
Hello Joel and Laura,

Please accept my apology for the lateness of the reply. I only received the response a minute ago and I am sending it directly to you.

Here is what I received:

Chlorpyrifos rates for Imported Fire Ant (IFA) quarantine uses:

∀ Containerized nursery stock

o Drench or immersion = 0.125 lb ai/100 gal water (current IFA regulation rate and labeled rate)

o Nursery owners under Federal IFA Quarantine are concerned about potentially losing the use of chlorpyrifos to treat containerized nursery stock due to EPA regulations. This concern is due to the fact that any slow-down in the movement of IFA-regulated articles out of a nursery greatly impacts the nursery's ability to stay competitive with nurseries that are not under quarantine. Due to the rapid exhibition of efficacy of chlorpyrifos, Federal regulations permit chlorpyrifos-treated containerized nursery stock to move out of quarantine within 24 hours of being treated. However, Federal regulations mandate that containerized nursery stock treated with alternative products, which days take several days to exhibit adequate efficacy, may not move out of quarantine for a number of days after they have been treated.

∀ Balled and burlapped nursery stock

o Drench or immersion = 0.125 lb ai/100 gal water (current IFA regulation rate and labeled rate)

o Currently, NO ALTERNATIVE CHEMICALS exist for treating balled and burlapped nursery stock in a manner that yields the same efficacy

∀ Grass sod

o Broadcast = 8 lb ai/acre is <u>current Federal IFA regulation rate</u>; currently no labels exist that permit this rate.

o Bearing in mind that Imported Fire Ant is considered to be a Public Health Pest, PPQ requests that EPA consider allowing labels to support this rate for Grass Sod. PPQ scientists have determined that the efficacy of chlorpyrifos using lower rates are **inadequate;** furthermore, importing countries will not accept grass sod from IFA quarantined areas without these high, efficacious treatment rates (i.e., lack of an appropriately labeled rate has been affecting export trade).

∀ Field grown nursery stock

o Broadcast of granular chlorpyifos = 6 lb ai/acre. This is the current Federal IFA regulation rate; no labels exist that permit this rate.

o Bearing in mind that Imported Fire Ant is considered to be a Public Health Pest, PPQ requests that EPA consider allowing labels to support this rate for Field grown nursery stock. PPQ scientists have determined that the efficacy of chlorpyrifos using lower rates are **inadequate.**

Please call or write if you would like to discuss these issues further.

Warm regards,

Susan O'Toole

National Pesticide Coordinator

Plant Protection and Quarantine

Animal and Plant Health Inspection Service

United States Department of Agriculture

4700 River Road, Unit 134

Riverdale, MD 20737

301-851-2243

sotoole@aphis.usda.gov

From: Wolf, Joel [mailto:Wolf.Joel@epa.gov]
Sent: Tuesday, June 23, 2015 3:51 PM
To: O'Toole, Susan J - APHIS; Laura Phelps
Subject: RE: Chlopyrifos and Imported Fire Ant Program

Thanks Susan. I will share it with others in case they haven't seen it yet. Best, Joel

From: O'Toole, Susan J - APHIS [mailto:Susan.J.O'Toole@aphis.usda.gov]
Sent: Tuesday, June 23, 2015 2:50 PM
To: Laura Phelps
Cc: Wolf, Joel
Subject: RE: Chlopyrifos and Imported Fire Ant Program

Hi Laura,

Our lead scientist is out of the office and I would like to speak with her before we give a definitive answer to EPA's question.

However, I would like to share with you and Mr. Wolf, a copy of the APHIS PPQ Imported Fire Ant Treatment Manual, which describes all Federally-required IFA treatments in detail. Perhaps it will be of help to EPA as they conduct their assessments . . . as you will see, the use sites cover a variety of nursery stock materials that are restricted from movement out of the IFA-quarantined areas until appropriate treatments are made.

Hope this helps.

Susan O'Toole

National Pesticide Coordinator

Plant Protection and Quarantine

Animal and Plant Health Inspection Service

United States Department of Agriculture

4700 River Road, Unit 134

Riverdale, MD 20737

301-851-2243

sotoole@aphis.usda.gov

From: Laura Phelps [mailto:Laura.Phelps@adama.com]
Sent: Monday, June 22, 2015 4:52 PM
To: O'Toole, Susan J - APHIS
Subject: FW: Chlopyrifos and Imported Fire Ant Program

See Joel's note- is there someone you might know to call who would have the answer?

From: Wolf, Joel [mailto:Wolf.Joel@epa.gov]
Sent: Monday, June 22, 2015 4:50 PM
To: Laura Phelps
Subject: RE: Chlopyrifos and Imported Fire Ant Program

Hi Laura,

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Thanks, Joel

From: Laura Phelps [mailto:Laura.Phelps@adama.com]
Sent: Monday, June 22, 2015 2:32 PM
To: Wolf, Joel
Subject: FW: Chlopyrifos and Imported Fire Ant Program

Hi Joel,

Please see the letter below from Susan at USDA. ADAMA would like to be sure to do what we can to protect this fire ant use. Is there anything I need to supply at this time to help in the review?

Thank you,

Laaura

Laura Phelps
Product Registration Manager
D +919-256-9329 | M +919-353-2439
E laura.phelps@us.adama.com

ADAMA

www.adama.com

From: O'Toole, Susan J - APHIS [mailto:Susan.J.O'Toole@aphis.usda.gov]
Sent: Monday, June 22, 2015 12:57 PM
To: Laura Phelps
Cc: Defeo, Valerie F - APHIS
Subject: Chlopyrifos and Imported Fire Ant Program

Hi Laura,

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Of great concern is its potential loss of use as a drench to treat balled and burlapped nursery stock, because there are no alternative chemicals registered for that use.

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It was nice speaking with you today. Kindly keep us in the loop if you hear anything about potential problems in retaining IFA uses.

Warm regards,

Susan O'Toole

National Pesticide Coordinator

Plant Protection and Quarantine

Animal and Plant Health Inspection Service

United States Department of Agriculture

4700 River Road, Unit 134

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USDA
United States Department of Agriculture

Imported Fire Ant: Quarantine Treatments for Nursery Stock, Grass Sod, and Related Materials

Animal and Plant Health Inspection Service

APHIS 81-25-001

Printed August 2013

Issued September 2013

This publication supersedes "Imported Fire Ant 2007: Quarantine Treatments for Nursery Stock and Other Regulated Articles," Program Aid No. 1904, which was issued in December 2006.

Photo credits: All photos are USDA-Animal and Plant Health Inspection Service (APHIS) file photos unless otherwise noted.

This document is intended to supplement and clarify the Federal Imported Fire Ant Quarantine (Title 7, *Code of Federal Regulations*, Part 301.81), the PPQ Treatment Manual, and the Imported Fire Ant Program Manual M301.81, which are published by USDA's Animal and Plant Health Inspection Service, Plant Protection and Quarantine. Approved quarantine treatments are subject to change. Always consult with your State plant regulatory agency before applying quarantine treatments.

Contents

General Information

Imported fire ants (IFA) are notorious hitchhikers and are readily transported long distances when articles such as soil, nursery stock, and other items are shipped outside the infested area. Provisions of the Federal Imported Fire Ant Quarantine (Title 7, *Code of Federal Regulations* [CFR], part 301.81) were invoked May 6, 1958, in an effort to slow or prevent the artificial spread of IFA (*Solenopsis invicta* Buren, *S. richteri* Forel, or their hybrids). Figure 1 depicts the parts of the United States quarantined for IFA as of December 2011.

Figure 1. Imported Fire Ant Quarantine map, December 2011.

This document offers a handy reference of treatment options for shipping regulated articles, such as nursery stock, from within the IFA quarantine area to a destination outside the IFA quarantine area (such as shipping from Louisiana to Illinois or Colorado). This includes shipments passing through non-quarantine areas, even if destined for another IFA quarantine area (such as shipping from Florida to Orange County, CA). If you are shipping nursery stock or another regulated article within the IFA quarantine area (such as from Georgia to Louisiana), you do NOT have to follow these Federal requirements, but you must check for any State regulations regarding other plant and soil pests.

The electronic APHIS-Plant Protection and Quarantine (PPQ) Treatment Manual is updated more frequently than this printed document. In order to have the most recent information regarding treatments, please routinely check the online PPQ Treatment Manual located at:
www.aphis.usda.gov/import_export/plants/manuals/ports/downloads/treatment.pdf.
Go to "Domestic Treatments" in the bookmarks section, then to "Imported Fire Ant (D301.81-10)".

The most recent IFA quarantine map is located at:
www.aphis.usda.gov/plant_health/plant_pest_info/fireants/downloads/fireant.pdf.

To determine whether you are in a quarantine area by your zip code, visit USDA's Web site at:
www.aphis.usda.gov/plant_health/plant_pest_info/fireants/zipcode.shtml and click the "check your zip code now" link.

The State plant regulatory officials/inspectors are your first line of communication regarding the Federal IFA Quarantine. See page 18 for a complete listing of State plant regulatory officials and USDA State Plant Health Directors in States regulated for IFA or go to:

State plant regulatory officials: www.nationalplantboard.org/member/index.html
USDA State Plant Health Directors: www.aphis.usda.gov/services/report_pest_disease/report_pest_disease.shtml

List of Regulated Articles

The following regulated articles require a certificate or permit before they can be shipped outside the IFA quarantine area. This document will address those articles associated with nurseries and sod growers (highlighted in red below).

1. IFA queens and reproducing colonies of IFA.
2. Soil, separately or with other things, except soil samples shipped to approved laboratories (consult with a State or Federal inspector for a list of approved laboratories). Potting soil is exempt if commercially prepared, packaged, and shipped in original container.
3. Plants with roots and soil attached, except house plants maintained indoors and not for sale.
4. Grass sod
5. Baled hay and straw that has been stored in contact with soil.
6. Used soil-moving equipment.
7. Any other products, articles, or means of conveyance of any character whatsoever not covered by the above, when it is determined by an inspector that they present a hazard of spread of the IFA and the person in possession thereof has been so notified.

Containerized nursery plants grown outside the greenhouse environment have the potential for IFA infestation.

Certificates authorizing movement of regulated articles are issued by quarantine officials when certain approved procedures have been utilized to ensure that the regulated article(s) are free from IFA infestation. Seepage 18 for a complete listing of State plant regulatory officials and USDA State Plant Health Directors.

Statutory Authorities Enabling Quarantine Action

Legislation enabling USDA to promulgate an IFA quarantine is part of the Plant Protection Act of June 2000 (7 United States Code [USC] 7701 et seq.)

Authorized Insecticides

Insecticides listed in this document have been registered under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA 7 USC § 135 et seq., 1972), as amended, or have been approved for use under an exemption (sections 18 or 24[c] of FIFRA). ***Instructions, precautions, and directions for use on the pesticide label must be carefully followed***As of March 2013, the following insecticides are approved by USDA for the treatment of regulated articles under the IFA quarantine. This list of labels is NOT inclusive, and an updated and detailed list of insecticide labels is available on the Web at: www.aphis.usda.gov/plant_health/plant_pest_info/fireants/downloads/IFA_QuarantineLables.pdf

Common Name	Trade Name examples	Formulations†	Use pattern
Bifenthrin	Talstar®, Onyx Pro®, etc. (many)	G, F, EC	Container, B&B, sod
Chlorpyrifos	Dursban®, Chlorpyrifos	E, G	Container, B&B, field grown, sod
Diazinon	Section 24(c) only, contact State plant regulatory official		
Fenoxycarb	Award®	Bait	Field grown
Fipronil	Topchoice®, Fipronil	G	Container, sod
Hydramethylnon	Amdro®Pro	Bait	Field grown
Methoprene	Extinguish®	Bait	Field grown
Pyriproxyfen	Distance®	Bait	Field grown
Tefluthrin	No label currently available	G	Container

† WP and W = wettable powder, E/EC = emulsifiable concentrate, G = Granular

Approved Treatments

Approved treatments for the various categories of regulated articles are contained in this section and in the PPQ Treatment Manual, which can be found online at:
www.aphis.usda.gov/import_export/plants/manuals/ports/downloads/treatment.pdf.
Go to "Domestic Treatments" in the bookmarks section, then to "Imported Fire Ant (D30181-10)". This online manual is updated within weeks of a new treatment being added to the approved treatments.

Nursery Stock in Containers

There are four methods for treating containerized nursery stock and different pesticides are approved for use in these methods.

- Immersion/Dip—bifenthrin and chlorpyrifos
- Drench—bifenthrin and chlorpyrifos
- Topical—bifenthrin
- Incorporation—bifenthrin, fipronil, and tefluthrin

Method 1—Immersion or Dip Treatment for Container Plants (not common for containerized stock)

Two insecticides are approved for this use pattern:

- Bifenthrin
- Chlorpyrifos

Equipment—An open-top, watertight immersion tank sufficiently large to accommodate the treating solution and plants will be needed. Drain plugs and valves will facilitate drainage after treatment. Use all personal protection equipment as required on the insecticide label. *Important: Do not allow runoff from the treatment area.*

Step 1—Choose an appropriate site.
- Locate the immersion tank in a well-ventilated place.

Step 2—Choose immersion tank.
- Choose an appropriate sized immersion tank that will allow complete submersion of the root/soil portion of the plant.
- Allow room for displacement of liquid solution as the plant is immersed so that no treatment liquid overruns the top of the tank.

Step 3—Immerse the plants.
- Do not remove plastic containers with drain holes before immersion.
- Immerse the containers, singly or in groups, so that the soil is completely covered by the insecticidal solution.
- Allow the plants to remain in the solution until bubbling ceases. Thorough saturation of the containers with the insecticide solution is essential.

Step 4—Remove the plants from the dip solution.
- After removal from the dip, set the plants on a drainboard until adequately drained.

Step 5—Maintain appropriate level of treating mixture.
- As treating progresses, add freshly prepared insecticide mixture to maintain the liquid at immersion depth.

Step 6—Dispose of solution.
- Dispose of tank contents 8 hours after mixing. Disposal must comply with label instructions, as well as State and local regulations.

Pesticides Approved, Dose Rates and Certification Periods for Immersion of Container Plants

Pesticide	Formulation	Dose Rate Lb ai/100 gal H2O	Certification Period
Chlorpryrifos*	EC	0.125 lb ai	30 days
Bifenthrin*	EC or F	0.115 lb ai	180 days
		0.05 lb ai	120 days
		0.025 lb ai	60 days

* use labels with use pattern listed on label

Exposure period—plants are certifiable upon completion of treatment (follow reentry interval [REI] instructions on label).

Caution: Environmental factors significantly affect phytotoxicity. It is recommended that a small group of plants be treated at the appropriate rate under the anticipated growing conditions and observed for phytotoxic symptoms for at least 7 days before a large number of plants are treated. Dwarf yaupon, some varieties of azaleas, camellias, poinsettias, rose bushes, and variegated ivy may show phytotoxicity to chlorpyrifos.

Method 2—Drench Treatment for Container Plants

Two insecticides are approved for this use pattern:

- Bifenthrin
- Chlorpyrifos

Equipment—A large-capacity bulk mixing tank, either pressurized or gravity flow, for mixing and holding the insecticide solution. Properly equipped hoses and watering nozzles that can be attached to the mixing tank and used to thoroughly saturate the container with the insecticide solution.

Step 1—If using bifenthrin determine dry weight bulk density of potting media (see page 17 for instructions).

Step 2—Choose an appropriate site with regard to potential runoff and ventilation.

Step 3—Determine amount of treating solution per container, total amount of treating solution required, and calibrate equipment.

- Volume of treating solution must be 1/5 (20 percent) the volume of the media in the container (minimum required).
- *Example*. A trade gal container is ca. 6"w x 7"h and in theory is ca. 3 quarts. If the container is filled within 1" of the top of the container, then use the height of 6". Therefore 1/5 volume of a trade gal container filled within 1" of the top is ca. 19 oz (rounding up).
- For many, calibrating is determined by how long (number of seconds) it takes for equipment to apply 19 oz (ca 2.5 cups) solution if treating all trade gallon containers.

Step 4—Treat containers.

- Apply treating solution to the point of saturation with a minimum of your predetermined 1/5 volume of a single container.

Step 5—Dispose of solution.

- Dispose of tank contents 8 hours after mixing. Disposal must comply with label instructions, as well as State and local regulations.

Pesticides Approved, Dose Rates and Certification Periods for Drench of Container Plants

Pesticide	Formulation	Rate of Application Amount formulation/100 gal H_2O or ppm	Certification Period
Chlorpryrifos*	4EC	4 fl oz	30 days
	2EC	8 fl oz	30 days
Bifenthrin*	23.4%EC	25 ppm**	180 days
	7.9%F	25 ppm**	180 days

* use labels with use pattern listed on label
** ppm based on dry weight bulk density of potting media, see table below and page 17 for instructions regarding bulk density determination.

Amount of Product by Formulation type to add to 100 gal water Based on Bulk Density of Potting Media

Potting media bulk density* lb/cu.yd.	Bifenthrin 7.9% flowable** Oz formulation/100 gal H_2O	Bifenthrin 23.4% EC** Oz formulation/100 gal H_2O
200	2.4	0.8
400	4.8	1.6
600	7.2	2.4
800	9.6	3.2
1,000	12.0	4.0
1,200	14.4	4.9
1,400	16.8	5.7

* see page 17 for instruction regarding bulk density determination.
** these rates are listed under High Drench Application Rate on labels

Exposure period—plants are certifiable upon completion of treatment (follow reentry interval [REI] instructions on label).

Diazinon may be registered by a State under FIFRA, sec. 24(c), Special Local Needs, for treatment of containerized non-bearing blueberries and fruit and nut plants. Check with your State regulatory official for 24(c) labels, treatment rates, and certification periods.

Caution: Environmental factors significantly affect phytotoxicity. It is recommended that a small group of plants be treated at the appropriate rate under the anticipated growing conditions and observed for phytotoxic symptoms for at least 7 days before a large number of plants are treated. Dwarf yaupon, some varieties of azaleas, camellias, poinsettias, rose bushes, and variegated ivy may show phytotoxicity to chlorpyrifos.

Method 3—Topical Treatment for Container Plants

This topical application method of treatment was developed when the Talstar®10WP formulation was the most common formulation available for bifenthrin. This formulation is no longer available for nursery uses, but the treatment language was transferred to the flowable and EC labels of bifenthrin. While this topical treatment is approved, it is not generally used.

One insecticide is approved for this use pattern:
- Bifenthrin

Caution: This method is approved only for treatment of nursery stock in 3- and 4-quart containers.

Step 1— Determine dry weight bulk density of potting media (see page 17 for instructions).

Step 2—Prepare treatment solution.

- Based on container size and bulk density of potting media, mix appropriate amount of bifenthrin in 1,000 oz water (or equivalent, based on number of pots to treat).
- Apply 1 fl oz of treating solution to each of the containers evenly distributed over the surface of the potting media.
- Irrigate all treated containers with 1.5 inches of water following treatment.

Pesticides Approved, Dose Rate and Certification Periods for Topical Drench of Container Plants

Potting media bulk density* Lb/cu yd	Bifenthrin 7.9% Flowable**		Bifenthrin 23.4% EC**		Certification Period
	Oz F/1,000 oz H_2O 3-qt pots	Oz F/1,000 oz H_2O 4-qt pots	Oz EC/1,000 oz H_2O 3-qt pots	Oz EC/1,000 oz H_2O 4-qt pots	
200	3.6	5.2	1.2	1.8	180 days
400	7.2	10.4	2.4	3.5	180 days
600	10.8	15.6	3.7	5.2	180 days
800	14.4	20.8	4.9	7.0	180 days
1,00	18.0	26.0	6.1	8.8	180 days
1,200	21.6	31.2	7.3	10.5	180 days
1,400	25.2	36.4	8.5	12.3	180 days

* see page 17 for instructions on dry weight bulk density determination
**use labels with use pattern listed on label

Exposure period – plants are certifiable upon completion of treatment (follow reentry interval [REI] instruction on label).

Method 4—Incorporation of Granular Insecticides into Potting Media for Container Plants

Three insecticides are approved for incorporation into potting media:

- Bifenthrin
- Fipronil
- Tefluthrin

Note: An online search conducted in March 2013 did not produce any fipronil or tefluthrin labels with this use pattern and rate of application.

<u>Equipment</u>—use soil-mixing equipment that will adequately mix and thoroughly blend the required dosage of pesticide throughout the potting media.

If you have your media prepared offsite by another company, granular insecticide may be premixed for you. However, once media is prepared and granular insecticide incorporated, the "clock" starts on the certification period. Therefore, to retain the maximum certification period for container stock, the premixed media should be used to pot nursery stock as soon as possible.

Step 1—Determine how long a certification period is required for the nursery stock you are potting.

Step 2—Determine dry weight bulk density of potting media (see page 17 for instructions).

Step 3—Calculate amount of granular product to mix per cubic yard of potting media based on dry weight bulk density, or use table from label.

Pesticides Approved, Dose Rate and Certification Periods for Incorporation of Granular Products into Potting Media for Container Plants

Insecticide*	Dose Rate (ppm)	Certification period
Bifenthrin	10	6 month
	12	12 month
	15	24 monnh
	25	Continuous**
Fipronil	10	6 month
	12	12 month
	15	24 month
	25	Continuous**
Tefluthrin	10	18 month
	25	Continuous**

* use labels with use pattern listed on label
** continuous certification if all other provisions of IFA Free Nursery Program are met (see page 11)

Amount of Granular Bifenthrin 0.2% Formulation to add to 1 cubic yard of Media Based on Dose Rate and Bulk Density of Potting Media

Dose Rate	Amt. of granular bifenthrin 0.2% based on bulk density of media (lb/cu yd)						
	200	300	400	500	600	800	1000
10	1.0	1.5	2.0	2.5	3.0	4.0	5.0
12	1.2	1.8	2.4	3.0	3.6	4.8	6.0
15	1.5	2.25	3.0	3.75	4.5	6.0	7.5
25	2.5	3.75	5.0	6.25	7.5	10.0	12.5

* see page 17 for instruction regarding bulk density determination .

Exposure period—plants are certifiable upon completion of treatment (follow reentry interval [REI] instructions on label).

Calculation for amount of granular insecticide to mix into 1 cubic yard of potting media based on known dry weight bulk density of media

$$\frac{\text{Bulk density of media x ppm}}{\text{Concentration of pesticide}} = \text{lb granular needed per cubic yard media}$$

Example: You want to treat 1 cubic yard of potting media with a bulk density of 500 lb/cu yd, with enough 0.2% granular bifenthrin for a 12-month certification period (12 ppm).

12 ppm = 12/1,000,000 = 0.000012
0.2% granular bifenthrin = 0.2/100 = 0.002

(500 x 0.000012)/0.002 = 3.0lb 0.2G bifenthrin/1 cu yd potting media

Note: Many nursery plants may require a longer certification than 24 months. When a plant is "potted up" into a larger container, the grower can use potting media with newly incorporated granular insecticide to surround and augment "old" media, therefore extending the certification period. For example, if a grower started a plant in a 1 gallon container on 3/1/10 with 12 ppm bifenthrin in the media, this plant now is certified for 12 months. On 2/28/11 (1 year later), the grower moves the plant into a 3-gallon container, and the potting media added to fill the container has been treated with 15 ppm bifenthrin. This plant may now be certified for an additional 24 months or until 2/28/13 (or for 24 months after the potting media was treated with the granular bifenthrin). This example illustrates the importance of recordkeeping to ensure the grower can verify certification of plants that have been repotted several times.

If the treatment in a container has "expired" (the certification period has been exceeded), there are two options:

1. Treat with an approved drench treatment, wait the REI period, then pot up as usual with media treated with granular insecticide for the certification period you desire.
2. Pot up the plant in non-treated media, and immediately drench the larger container with an approved drench treatment. This plant will then have the drench certification period (up to 6 months with a bifenthrin drench) before it will require an additional drench or another potting up with media treated with granular insecticide for the certification period you desire.

Federal IFA-Free Nursery Program for Plants in Containers

This IFA-Free Nursery Program is not mandatory for movement of nursery stock. Certification may be granted on the basis of other treatments listed on pages 6–10 of this document.

The IFA-Free Nursery Program is designed to keep nurseries free of IFA and provides a basis to certify containerized nursery stock on a continuous basis. The program has detection, control, exclusion, and enforcement components that, in combination, provide maximum control of IFA. This program is available for growers who wish to include the entire property in their IFA treatment program and thus be able to ship container stock on a continuous basis. Participating establishments must operate under a compliance agreement. Few nurseries participate in this program, but it is available for use. Please contact your State inspector to discuss whether this program is right for your nursery. Specific details may be found in the *Code of Federal Regulations* (7 CFR 301.81–11: Imported fire ant detection, control, exclusion, and enforcement program for nurseries producing containerized plants). This regulation is updated annually, so please go to the USDA, APHIS link to the current *Code of Federal Regulations* information: www.aphis.usda.gov/plant_health/plant_pest_info/fireants/index.shtml

Nursery Stock—Field-Grown and Balled-and-Burlapped (B&B) Stock

There are three methods for treating field grown nursery stock, and different pesticides are approved for use in these methods—two post-harvest and one pre-harvest:

- Post-harvest B&B treatments
  - Immersion/Dip—bifenthrin and chlorpyrifos
  - Drench—chlorpyrifos
- Pre-harvest in field treatment—broadcast bait plus broadcast contact insecticide (chlorpyrifos)

Method 1—Immersion or Dip Treatment for Balled-and-Burlapped (B&B) Plants

Two insecticides are approved for this use pattern:
- Bifenthrin
- Chlorpyrifos

<u>Equipment</u>—An open-top, watertight immersion tank sufficiently large to accommodate the treating solution and plants will be needed. Drain plugs and valves will facilitate drainage after treatment. Use all personal protection equipment as required on the insecticide label and State and Federal laws. *Important: Do not allow runoff from the treatment area.*

Step 1—Choose an appropriate site.
- Locate the immersion tank in a well-ventilated place. The location should be covered if possible.

Step 2—Choose immersion tank.
- Choose an appropriate sized immersion tank that will allow complete submersion of the root/soil portion of the plant.
- Allow room for displacement of liquid solution as the root ball is immersed so that no treatment liquid over-runs the top of the tank.

Step 3—Immerse the plants.
- Do not remove burlap before immersion.
- Immerse the root balls, singly or in groups, so that the root ball is completely covered by the insecticidal solution.
- Allow the plants to remain in the solution until bubbling ceases. Thorough saturation of the root ball with the insecticide solution is essential.

Step 4—Remove the plants from the dip.
- After removal from the dip, set the plants on a drainboard until adequately drained.

Step 5—Maintain appropriate level of treating mixture.
- As treating progresses, add freshly prepared insecticide mixture to maintain the liquid at immersion depth.

Step 6—Dispose of solution.
- Dispose of tank contents 8 hours after mixing. Disposal must comply with label instructions, as well as, State and local regulations.

Pesticides Approved, Dose Rates and Certification Periods for Immersion of Balledand-Burlapped Plants

Pesticide	Formulation	Dose Rate Lb ai/100 gal H2O	Certification Period
Chlorpryrifos*	EC	0.125 lb ai	30 days
Bifenthrin*	EC or F	0.115 lb ai	180 days
		0.05 lb ai	120 days
		0.025 lb ai	60 days

* use labels with use pattern listed on label

Exposure period—plants are certifiable upon completion of treatment (follow reentry interval [REI] instructions on label).

Caution: Environmental factors significantly affect phytotoxicity. It is recommended that a small group of plants be treated at the appropriate rate under the anticipated growing conditions and observed for phytotoxic symptoms for at least 7 days before a large number of plants are treated. Dwarf yaupon, some varieties of azaleas, camellias, poinsettias, rose bushes, and variegated ivy may show phytotoxicity to chlorpyrifos.

Method 2—Drench Treatment for B&B Plants

One insecticide is approved for this use pattern:

- Chlorpyrifos

Equipment—A large-capacity bulk mixing tank, either pressurized or gravity flow, for mixing and holding the insecticide solution. Properly equipped hoses and watering nozzles that can be attached to the mixing tank and used to thoroughly saturate the root ball with the insecticide solution. Use all personal protection equipment as required by the insecticide label and State or Federal laws.

Step 1—Select a site for the treatment.

- Move the plants to a well-ventilated place normally used to maintain plants prior to shipment.
- Choose an appropriate site with regard to potential runoff and ventilation.

Step 2—Determine amount of treating solution per root ball, total amount of treating solution required and calibrate equipment.

- Treating to runoff will mean total volume of treating solution is approximately 1/5 (20 percent) the volume of the root ball.
- Volume formula for Cone = pi (R^2 + rR + r^2) h / 3 where R = Radius of top of cone, r = radius of bottom of cone, h = cone height, pi = 3.14.
  - *Example*. If you have a 25" root ball (top diameter) with a bottom diameter of ca. 10" and a height of ca. 12", the volume of the root ball is ca. 3061.5 cu inches or ca. 13.3 gal (using online conversion page).
  - 1/5 of 13.3 gal is ca. 2.6 gal treatment solution to be used over the course of the 6 drench applications (or ca. 0.45 gal per drench application).
  - Your State inspector or an extension agent can assist you with this calculation.
- For many, calibrating is determined by how long (number of seconds) it takes for equipment to apply 0.45 gal solution if treating all 25" root balls.

Step 3—Apply the treatment.

- The treatment will be enhanced by adding any agricultural wetting agent or surfactant.
- Do not remove burlap wrap from plants prior to treatment .
- Apply the insecticide solution as a substitute for plain water to the plants during the routine watering activities.
- Treat plants with the insecticide solution to the point of runoff (see above) on a twice daily schedule for 3 consecutive days.
- Rotate or flip the root ball between applications to ensure all sides of the root ball are sufficiently treated.

Step 4—Dispose of solution.

- Dispose of tank contents 8 hours after mixing. Disposal must comply with label instructions, as well as, State and local regulations.

Pesticides Approved, Dose Rates and Certification Periods for Drench of Balledand-Burlapped Plants

Pesticide	Formulation	Amt formulation/ 100 gal H_2O	Dose Rate Lb ai/100 gal H_2O	Certification Period
Chlorpryrifos*	4EC	4 fl oz	0.125 lb ai	30 days
	2EC	8 fl oz	0.125 lb ai	30 days

* use labels with use pattern listed on label

Exposure period—plants are certifiable upon completion of treatment (follow reentry interval [REI] instructions on label).

Method 3 – In field treatment of Field-Grown Plants (Pre-Harvest)

Several bait products and one contact insecticide are approved for this use pattern:

- Baits
  - Fenoxycarb
  - Hydramethylnon
  - Methoprene
  - Pyriproxyfen
- Contact insecticide
  - Chlorpyrifos granular

Note: An online search conducted in March 2013 did not produce any chlorpyrifos labels with this use pattern and rate of application.

This in-field treatment is based on a sequential application of an approved bait followed by a broadcast application of a contact insecticide. The combination treatment is necessary since broadcast application of chlorpyrifos (or other short-term residual insecticides) usually does not eliminate large, mature IFA colonies, and baits are not capable of providing a residual barrier against reinfestation by new queens. Therefore, the approved bait application will drastically reduce the IFA population, while the contact insecticide (chlorpyrifos), applied approximately 5 days later, will destroy any remaining weakened colonies and also leave a residual barrier against reinfestation by newly mated queens for a period of time (certification period).

Pesticides Approved, Dose Rates, Exposure Periods, and Certification Periods for Infield Treatment of Field Grown Plants

Apply bait	3-5 days later apply contact	Exposure Period	Certification Period
Approved bait @ 1-1.5 lb ai/acre Fenoxycarb Hydramethylnon Methoprene Pyriproxyfen	Chlorpyrifos G @ 6 lb ai/acre	30 days after contact application	12 weeks after exposure period
	2^{nd} chlorpyrifos application at 6 lb ai/acre at end of original certification period		12 weeks additional certification

Note: Treatment area must extend at least 10 feet beyond the base of all plants that are to be certified.

Apply the bait with any granular applicator capable of applying labeled rates of 1-1.5 lb bait per acre. Baits should be applied when ants are actively foraging, usually when air temperatures are between 65-90 °F. To determine if ants are active, place a food lure such as slices of hotdogs or potato chips in the area you plan to treat, wait ca. 30-45 minutes, and check the food lure for ants. Most seed or fertilizer granular applicators cannot be accurately calibrated to this low rate. A Herd® GT-77 Granular Applicator (Kasco Manufacturing; Shelbyville, IN) is frequently used in conjunction with all-terrain vehicles or farm tractors to apply IFA baits.

Grass Sod

There are three insecticides approved for treatment of grass sod. All treatments require broadcast application and an exposure period prior to the certification period.

- Bifenthrin—liquid
- Chlorpyrifos—liquid
- Fipronil—granular

Note: An online search conducted in March 2013 did not produce any chlorpyrifos labels with this use pattern and rate of application.

All treatments are applied as broadcast treatments with appropriate ground application equipment. Liquid treatments (chlorpyrifos or bifenthrin) should be applied at the rate of finished solution per acre as noted on the specific label, or the addition of an appropriate surfactant used at lower rates/acre of application. Read labels carefully. All treatments will benefit from irrigation after treatment, so it is recommended that onehalf inch of irrigation be added after treatment.

Pesticides Approved, Dose Rates and Certification Periods for Broadcast Treatment of Grass Sod

Pesticide	Formulation	lb ai/acre per application	Total no. applications 1 week apart	Total lb ai/acre	Exposure Period	Certification Period
Bifenthrin	EC	0.2	2	0.4	28 days	16 wks
Chlorpyrifos	EC, WP	8	1	8	2 days	6 wks
Fipronil	G	0.0125	2	0.025	30 days	20 wks

Example: You are applying liquid bifenthrin to 10 acres of grass sod in the IFA quarantine area. Using a broadcast applicator, apply 0.2 lb. active ingredient (ai) per acre in an appropriate amount of water, and then 7 days later, apply a second dosage of 0.2 lb. a.i. per acre. After a 28-day exposure period, you may harvest and ship sod for 16 weeks. After that time, to continue harvesting from the same area, you would need to re-treat if allowed by the label.

Greenhouse-Grown Plants

Greenhouse-grown plants are certifiable without insecticidal treatment if the inspector determines that the greenhouse is constructed of fiberglass, glass, or plastic in such a way that IFA are physically excluded and cannot become established within the enclosure. Slat houses, shade houses, or open greenhouses do not qualify as physical barriers. Plants grown in these structures must be treated with an approved insecticide before they can be certified for movement.

Blueberries and Other Fruit and Nut Nursery Stocks

Certain States may have Special Local Needs labeling in accordance with section 24(c) of FIFRA for diazinon, which APHIS will recognize as a regulatory treatment for containerized nonbearing blueberries and fruit and nut plants. Follow label directions for use. Contact your State regulatory official for availability and instructions.

Soil Samples

Soil samples are eligible for movement when treated by heat or cold temperatures. Samples are certified for as long as the soil is protected from recontamination after the appropriate exposure period.

Treatment	Temperature °F (°C)	Exposure Period
Heat—dry or steam	150 °F (65.5 °C)	Until all parts of mass reach 150 °F
Cold—freezing	-10 °F to -20 °F (-23 °C to -28 °C)	24 hours minimum

Soil samples may be frozen in any commercial cold storage, frozen food locker, or home freezer capable of rapidly reducing to and maintaining required temperature. Soil samples will be placed in plastic bags—one sample per bag. The bags will be arranged in the freezer in a manner to allow the soil samples to freeze in the fastest possible time. If desired, the frozen samples may be shipped in one carton. Soil samples destined for an approved laboratory do not require treatment. Check with your State regulatory official or USDA State Plant Health Director for a list of approved laboratories.

Certification of Regulated Articles

All regulated articles moving interstate and outside the IFA Quarantine area must demonstrate compliance with the IFA Quarantine regulations (7 CFR 301.81). Establishments that regularly ship large quantities of regulated articles (nursery stock) outside the regulated area should enter into a compliance agreement.A compliance agreement is reviewed on a regular basis, and through this agreement, the grower is issued a stamp, a written statement or other means of certifying each shipment. Establishments that rarely ship outside the regulated area will need to call their State inspector several weeks prior to shipment and have each load issued a certificate or limited permit demonstrating compliance with the IFA regulations. This will require the inspector to be present for any treatments required prior to shipment.Contact your State inspector for details.

Recordkeeping

Recordkeeping for all restricted-use pesticides (RUPs) is required by FIFRA, 40 CFR Part 171, and the Food, Agriculture, Conservation and Trade (FACT) Act of 1990, commonly referred to as the 1990 Farm Bill. Section 11 of FIFRA and 40 CFR Part 171 require certified commercial applicators to maintain records of application of RUPs. The 1990 Farm Bill requires private pesticide applicators to keep records of restricted-use chemicals they apply (www.ams.usda.gov/AMSv1.0/pesticiderecords). Many State pesticide laws, including those for recordkeeping, are more extensive than Federal law, and certified private and commercial applicators must familiarize themselves with the State's pesticide laws and recordkeeping requirements.

Under Federal law, commercial applicators and those who contract with commercial applicators to apply RUPs to property owned by another person must maintain applicator records for at least 24 months from the date of pesticide use, and they shall include the following information [40 CFR 171.11(c)(7)]:

- Name and address of the person for whom the pesticide was applied;
- Location of the pesticide application;
- Target pest(s);
- Specific crop or commodity, as appropriate, and site, to which the pesticide was applied;
- Year, month, day, and time of application;
- Trade name and Environmental Protection Agency (EPA) registration number of the pesticide applied;
- Amount of the pesticide applied and percentage of active ingredient per unit of the pesticide used; and
- Type and amount of the pesticide disposed of, method of disposal, date(s) of disposal, and location of the disposal site.

Under Federal law, private applicators must maintain applicator records for at least 2 years. The nine required elements that must be recorded within 14 days of each RUP application are as follows (1990 Farm Bill):

- The brand or product name
- The EPA registration number
- The total amount applied
- The month, day, and year
- The location of the application
- The crop, commodity, stored product, or site
- The size of area treated
- The name of the certified applicator
- The certification number of the certified applicator

Approved State plans for certification of commercial and private applicators must include provisions requiring certified commercial applicators to keep and maintain for the period of at least 2 years routine operational records containing information on types, amounts, uses, dates, and places of application of RUPs, and for ensuring that such records will be available to appropriate State officials.

The term commercial applicator means a certified applicator (whether or not he/she is a private applicator with respect to some uses) who uses or supervises the use of any pesticide which is classified for restricted use for any purpose or on any property other than as provided by the definition of “private applicator.”

The term private applicator means a certified applicator who uses or supervises the use of any pesticide which is classified for restricted use for purposes of producing any agricultural commodity on property owned or rented by him/her or his/her employer or (if applied without compensation other than trading of personal services between producers of agricultural commodities) on the property of another person.

Many State pesticide agencies have developed recordkeeping forms for your convenience. Check with your State regarding specifics on recordkeeping requirements and forms. For States operating under Federal law for private applicator recordkeeping, forms are available at: www.ams.usda.gov/AMSv1.0/pesticiderecords.

Mitigative Measures

The following measures are required to minimize the impact of quarantine treatments on the environment and human health. Any person requesting certification to authorize the movement of regulated articles must adhere to these measures where applicable.

- All applicable Federal, State, and local environmental laws and regulations must be followed.
- Safety equipment and clothing (personal protective equipment [PPEs]), as specified by the label instructions, must be used and worn during treatments and inspections.
- Safety practices shall be communicated, and regulated establishment managers must require that on-the-job safety practices be followed.
- All pesticides must be applied, handled, stored, and used in accordance with label instructions.
- Empty pesticide containers must be disposed of in accordance with label instructions and Federal, State, and local regulations.
- Pesticide remaining in containers after completion of an application must be retained and disposed of in accordance with label instructions and Federal, State, and local regulations.
- Oral or written warnings must be provided to workers and the general public, indicating pesticide application areas during application and appropriate re-entry intervals (REIs).
- Owners or managers of regulated properties must take precautions to limit access to treated areas by the public, livestock, and wildlife.

Protocol for Collection of Nursery Potting Media for Bulk Density Determination

Contact your State regulatory official/inspector (see page 17) prior to collecting samples to determine where to submit samples and any costs associated with the work.

If the State does not provide specific instructions for sample collection, the following protocol can be used:

- Collect potting media from five different locations around the media pile for a total of approximately one-half gallon of media, and place in a heavy duty plastic bag. Do this for each different media type you want bulk density determined for. Double bagging may be necessary to ensure against breakage during shipping.
- If a sample form is not supplied by the State, please include with each sample:
    - Contact person name, phone number, mailing address, and email address;
    - Date sample collected;
    - Requested service: bulk density determination; and
    - Any additional remarks or comments, as needed.

State Plant Regulatory Officials (www.nationalplantboard.org/member/index.html)

Alabama
AL Department of Agriculture and Industries
Division of Plant Industry
1445 Federal Drive
Montgomery, AL 36107
334-240-7225

Arizona
Plant Services Division
Arizona Department of Agriculture
1688 West Adams
Phoenix, AZ 85007
602-542-0996

Arkansas
Division of Plant Industry
Arkansas State Plant Board
Post Office Box 1069
Little Rock, AR 72203
501-225-1598

California
Plant Health and Pest Prevention Services
California Department of Food & Agriculture
1220 N Street, Room 221
Sacramento, CA 95814
916-654-0317

Florida
Division of Plant Industry
Florida Dept. of Agriculture & Consumer Services
Post Office Box 147100
Gainesville, FL 32614-7100
352-395-4628

Georgia
Plant Protection Section
Georgia Department of Agriculture
1109 Experiment Street
Redding Building, Room 213
Griffin, GA 30223
404-586-1140

Louisiana
Louisiana Department of Agriculture and Forestry
Post Office Box 3596
Baton Rouge, LA 70821-3596
225-952-8100

Mississippi
Bureau of Plant Industry
Mississippi Department of Agriculture and Commerce
Post Office Box 5207
Mississippi St., MS 39762
662-325-8789

New Mexico
Bureau of Entomology & Nursery Industries
New Mexico Department of Agriculture MSC, 3BA
Post Office Box 30005
Las Cruces, NM 88003-0005
575-646-3207

North Carolina
North Carolina Department of Agriculture and Consumer Services
Plant Industry Division
1060 Mail Service Center
Raleigh, NC 27699-1060
919-707-3753

Oklahoma
Consumer Protection Services Division
Oklahoma Department of Agriculture, Food and Forestry
Post Office Box 528804
Oklahoma City, OK 73152-8804
405-522-5879

Puerto Rico
State Plant Quarantine Program
Puerto Rico Department of Agriculture
Post Office Box 10163
San Juan, PR 00908-1163
787-723-7725, 787-722-5301

South Carolina
Department of Plant Industry
511 Westinghouse Road
Pendleton, SC 29670
864-646-2135

Tennessee
Division of Regulatory Services
Tennessee Department of Agriculture
Post Office Box 40627
Melrose Station
Nashville, TN 37204
615-837-5338

Texas
Texas Department of Agriculture
Post Office Box 12847
Austin, TX 78711
512-463-5025

Virginia
Office of Plant and Pest Services
Virginia Department of Agriculture and Consumer Services
Post Office Box 1163
Richmond, VA 23218
804-786-3515

USDA, APHIS, State Plant Health Directors (www.aphis.usda.gov/services/report_pest_disease/report_pest_disease.shtml)

Alabama
USDA, APHIS, PPQ, SPHD
1st Floor ADP RM
1836 Glynwood Drive
Prattville, AL 36066
334-358-4920

Arizona
USDA, APHIS, PPQ, SPHD for AZ & NM
3640 E Wier Ave.
Phoenix, AZ 85040
602-431-3200

Arkansas
USDA, APHIS, PPQ, SPHD
1200 Cherrybrook Drive, Suite 100
Little Rock, AR 72211-3861
501-324-5258

California
USDA, APHIS, PPQ, SPHD
650 Capital Mall, Suite 6-400
Sacramento, CA 95814
916-930-5500

Florida
USDA, APHIS, PPQ, SPHD
8100 NW 15th Place
Gainesville, FL 32606
352-313-3040

Georgia
USDA, APHIS, PPQ, SPHD
1506 Klondike Road, Suite 306
Conyers, GA 30094
770-860-4020

Louisiana
USDA, APHIS, PPQ, SPHD
4354 S. Sherwood Forest Boulevard., Suite 150
Baton Rouge, LA 70816
225-298-5410

Mississippi
USDA, APHIS, PPQ, SPHD
505 Russell Street
Starkville, MS 39759
662-323-1291

New Mexico
USDA, APHIS, PPQ, SPHD
3640 E Wier Avenue
Phoenix, AZ 85040
602-431-3200

North Carolina
USDA, APHIS, PPQ, SPHD for NC & SC
930 Main Campus Drive, Suite 200
Raleigh, NC 27606-5202
919-855-7600

Oklahoma
USDA, APHIS, PPQ, SPHD
301 N. W. 6th Street, Suite 101
Oklahoma City, OK 73105
405-609-8840

Puerto Rico
USDA, APHIS, PPQ, SPHD
IBM Building
654 Muñoz Rivera Avenue, Suite 700
Hato Rey, PR 00918
787-766-6050

South Carolina
USDA, APHIS, PPQ, SPHD for NC & SC
930 Main Campus Dr., Suite 200
Raleigh, NC 27606
919-855-7600

Tennessee
USDA, APHIS, PPQ, SPHD
1410 Kensington Square Court, Suite 101
Murfreesboro, TN 37130-6902
615-907-3357

Texas
USDA, APHIS, PPQ, SPHD
903 San Jacinto Boulevard, Suite 270
Austin, TX 78701-2450
512-916-5241

Virginia
USDA, APHIS, PPQ, SPHD
5657 South Laburnum Avenue
Richmond, VA 23231-4536
804-771-2042

To: O'Toole, Susan J - APHIS[Susan.J.O'Toole@aphis.usda.gov]; Laura Phelps[Laura.Phelps@adama.com]
From: Wolf, Joel
Sent: Mon 7/13/2015 1:36:45 PM
Subject: RE: Chlopyrifos and Imported Fire Ant Program

Thanks Susan. This is helpful. If I or others have questions I'll let you know.

Best, Joel

From: O'Toole, Susan J - APHIS [mailto:Susan.J.O'Toole@aphis.usda.gov]
Sent: Thursday, July 09, 2015 4:54 PM
To: Wolf, Joel; Laura Phelps
Subject: RE: Chlopyrifos and Imported Fire Ant Program

Hello Joel and Laura,

Please accept my apology for the lateness of the reply. I only received the response a minute ago and I am sending it directly to you.

Here is what I received:

Chlorpyrifos rates for Imported Fire Ant (IFA) quarantine uses:

•□□□□□□□□ Containerized nursery stock

o Drench or immersion = 0.125 lb ai/100 gal water (current IFA regulation rate and labeled rate)

o Nursery owners under Federal IFA Quarantine are concerned about potentially losing the use of chlorpyrifos to treat containerized nursery stock due to EPA regulations. This concern is due to the fact that any slow-down in the movement of IFA-regulated articles out of a nursery greatly impacts the nursery's ability to stay competitive with nurseries that are not under quarantine. Due to the rapid exhibition of efficacy of chlorpyrifos, Federal regulations permit chlorpyrifos-treated containerized nursery stock to move out of quarantine within 24 hours of being treated. However, Federal regulations mandate that containerized nursery stock treated with alternative products, which days take several days to exhibit adequate efficacy, may not move out of quarantine for a number of days after they have been treated.

•□□□□□□□□ Balled and burlapped nursery stock

o Drench or immersion = 0.125 lb ai/100 gal water (current IFA regulation rate and labeled rate)

o Currently, NO ALTERNATIVE CHEMICALS exist for treating balled and burlapped nursery stock in a manner that yields the same efficacy

•□□□□□□□□ Grass sod

o Broadcast = 8 lb ai/acre is current Federal IFA regulation rate; currently no labels exist that permit this rate.

o Bearing in mind that Imported Fire Ant is considered to be a Public Health Pest, PPQ requests that EPA consider allowing labels to support this rate for Grass Sod. PPQ scientists have determined that the efficacy of chlorpyrifos using lower rates are **inadequate;** furthermore, importing countries will not accept grass sod from IFA quarantined areas without these high, efficacious treatment rates (i.e., lack of an appropriately labeled rate has been affecting export trade).

•□□□□□□□□ Field grown nursery stock

o Broadcast of granular chlorpyifos = 6 lb ai/acre. This is the current Federal IFA regulation rate; no labels exist that permit this rate.

o Bearing in mind that Imported Fire Ant is considered to be a Public Health Pest, PPQ requests that EPA consider allowing labels to support this rate for Field grown nursery stock. PPQ scientists have determined that the efficacy of chlorpyrifos using lower rates are **inadequate.**

Please call or write if you would like to discuss these issues further.

Warm regards,

Susan O'Toole

National Pesticide Coordinator

Plant Protection and Quarantine

Animal and Plant Health Inspection Service

United States Department of Agriculture

4700 River Road, Unit 134

Riverdale, MD 20737

301-851-2243

sotoole@aphis.usda.gov

From: Wolf, Joel [mailto:Wolf.Joel@epa.gov]
Sent: Tuesday, June 23, 2015 3:51 PM
To: O'Toole, Susan J - APHIS; Laura Phelps
Subject: RE: Chlopyrifos and Imported Fire Ant Program

Thanks Susan. I will share it with others in case they haven't seen it yet. Best, Joel

From: O'Toole, Susan J - APHIS [mailto:Susan.J.O'Toole@aphis.usda.gov]
Sent: Tuesday, June 23, 2015 2:50 PM
To: Laura Phelps
Cc: Wolf, Joel
Subject: RE: Chlopyrifos and Imported Fire Ant Program

Hi Laura,

Our lead scientist is out of the office and I would like to speak with her before we give a definitive answer to EPA's question.

However, I would like to share with you and Mr. Wolf, a copy of the APHIS PPQ Imported Fire Ant Treatment Manual, which describes all Federally-required IFA treatments in detail. Perhaps it will be of help to EPA as they conduct their assessments . . . as you will see, the use sites cover a variety of nursery stock materials that are restricted from movement out of the IFA-quarantined areas until appropriate treatments are made.

Hope this helps.

Susan O'Toole

National Pesticide Coordinator

Plant Protection and Quarantine

Animal and Plant Health Inspection Service

United States Department of Agriculture

4700 River Road, Unit 134

Riverdale, MD 20737

301-851-2243

sotoole@aphis.usda.gov

From: Laura Phelps [mailto:Laura.Phelps@adama.com]
Sent: Monday, June 22, 2015 4:52 PM
To: O'Toole, Susan J - APHIS
Subject: FW: Chlopyrifos and Imported Fire Ant Program

See Joel's note- is there someone you might know to call who would have the answer?

From: Wolf, Joel [mailto:Wolf.Joel@epa.gov]
Sent: Monday, June 22, 2015 4:50 PM
To: Laura Phelps
Subject: RE: Chlopyrifos and Imported Fire Ant Program

Hi Laura,

I did have one question. Do you know what the lowest effective application rate is, in your opinion, for the fire ant use?

Thanks, Joel

From: Laura Phelps [mailto:Laura.Phelps@adama.com]
Sent: Monday, June 22, 2015 2:32 PM
To: Wolf, Joel
Subject: FW: Chlopyrifos and Imported Fire Ant Program

Hi Joel,

Please see the letter below from Susan at USDA. ADAMA would like to be sure to do what we can to protect this fire ant use. Is there anything I need to supply at this time to help in the review?

Thank you,

Laaura

Laura Phelps

E laura.phelps@us.adama.com

Product Registration Manager
D +919-256-9329 | M +919-353-2439

ADAMA

www.adama.com

From: O'Toole, Susan J - APHIS [mailto:Susan.J.O'Toole@aphis.usda.gov]
Sent: Monday, June 22, 2015 12:57 PM
To: Laura Phelps
Cc: Defeo, Valerie F - APHIS
Subject: Chlopyrifos and Imported Fire Ant Program

Hi Laura,

Thank you for taking the time to speak with me at noon today and for letting me know that ADAMA is willing to support the IFA uses currently listed on ADAMA and associated distributor labels.

As I mentioned over the phone, PPQ's Imported Fire Ant (IFA) Program desires to retain all uses of chlorpyrifos currently contained on all labels by ADAMA or their distributors.

Of great concern is its potential loss of use as a drench to treat balled and burlapped nursery stock, because there are no alternative chemicals registered for that use.

Also of concern is the potential loss of use of chlorpyrifos to treat containerized nursery stock. This concern is due to the fact that any slow-down in the movement of IFA-regulated articles out of a nursery greatly impacts the nursery's ability to stay competitive. Due to the rapid exhibition of efficacy of chlorpyrifos, Federal regulations permit chlorpyrifos-treated containerized nursery stock to move out of quarantine within 24 hours of being treated. However, regulations mandate that containerized nursery stock treated with alternative products, which days take days to exhibit adequate efficacy, may not move out of quarantine for a number of days after they have been treated.

Attached please find a list of products whose labels permit appropriate uses of chlorpyrifos to target fire ant on containerized and balled-and-burlapped nursery stock. There may be other labels in existence – we are not completely sure of all the distributors' labels available at this point.

I understand from you the following:

1. Dow is the lead negotiator with EPA on the Registration Review process;

2. Dow has removed all IFA uses of chlopyrifos from their labels and does not intend to get involved with IFA uses;

3. That the EFED evaluation, which has not yet been completed, may address IFA uses, and that the HED review is completed.

It was nice speaking with you today. Kindly keep us in the loop if you hear anything about potential problems in retaining IFA uses.

Warm regards,

Susan O'Toole

National Pesticide Coordinator

Plant Protection and Quarantine

Animal and Plant Health Inspection Service

United States Department of Agriculture

4700 River Road, Unit 134

Riverdale, MD 20737

301-851-2243

sotoole@aphis.usda.gov

To: O'Toole, Susan J - APHIS[Susan.J.O'Toole@aphis.usda.gov]; Laura Phelps[Laura.Phelps@adama.com]
From: Wolf, Joel
Sent: Tue 6/23/2015 7:50:54 PM
Subject: RE: Chlopyrifos and Imported Fire Ant Program

Thanks Susan. I will share it with others in case they haven't seen it yet. Best, Joel

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Sent: Tuesday, June 23, 2015 2:50 PM
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Cc: Wolf, Joel
Subject: RE: Chlopyrifos and Imported Fire Ant Program

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National Pesticide Coordinator

Plant Protection and Quarantine

Animal and Plant Health Inspection Service

United States Department of Agriculture

4700 River Road, Unit 134

Riverdale, MD 20737

301-851-2243

sotoole@aphis.usda.gov

From: Laura Phelps [mailto:Laura.Phelps@adama.com]
Sent: Monday, June 22, 2015 4:52 PM
To: O'Toole, Susan J - APHIS
Subject: FW: Chlopyrifos and Imported Fire Ant Program

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From: Wolf, Joel [mailto:Wolf.Joel@epa.gov]
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Thank you,

Laaura

Laura Phelps
Product Registration Manager
D +919-256-9329 | M +919-353-2439
E laura.phelps@us.adama.com

ADAMA

www.adama.com

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Sent: Monday, June 22, 2015 12:57 PM
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Cc: Defeo, Valerie F - APHIS
Subject: Chlopyrifos and Imported Fire Ant Program

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Warm regards,

Susan O'Toole

National Pesticide Coordinator

Plant Protection and Quarantine

Animal and Plant Health Inspection Service

United States Department of Agriculture

4700 River Road, Unit 134

Riverdale, MD 20737

301-851-2243

sotoole@aphis.usda.gov

To: Sack, Chris A[Chris.Sack@fda.hhs.gov]; anna.shulkin@syngenta.com[anna.shulkin@syngenta.com]; Doherty, Michael[Doherty.Michael@epa.gov]; Holman, Elizabeth[Holman.Elizabeth@epa.gov]; petellep@croplife.ca[petellep@croplife.ca]; Monique Thomas[Monique.Thomas@hc-sc.gc.ca]
From: Tiu, Carmen (C)
Sent: Mon 5/18/2015 8:18:31 PM
Subject: FW: [CLA-REWG] FW: Agenda REWG May 19-20 [3 Attachments]
CLA May 2015.pptx
DRAFT_CCPR47_REP15_PRe.pdf
REWG_Agenda_May_19_20 rsm.docx

Dear All,

You are also all cordially invited to participate for the topics of your interest. See call-in information in the Agenda, make sure to pick on the second option listed. Let me know if anyone has any question that I can help with.

Many thanks and best regards,

Carmen Tiu

CLA-REWG Chair

From: CLA-REWG@yahoogroups.com [mailto:CLA-REWG@yahoogroups.com] **On Behalf Of** Ray McAllister rmcallister@croplifeamerica.org [CLA-REWG]
Sent: Monday, May 18, 2015 3:30 PM
To: 'CLA-REWG@yahoogroups.com'
Cc: Caldera, Mayra FAS (Mayra.Caldera@fas.usda.gov); Rasmussen, Mark - FAS; Madden, Barbara; Miller, David; Nguyen, James; Haynes, Diana - AMS; Williams Ron
Subject: [CLA-REWG] FW: Agenda REWG May 19-20 [3 Attachments]

TO: Residue Experts Work Group (and guests)

FROM: Ray S. McAllister, PhD

Senior Director, Regulatory Policy

CropLife America

202-872-3874 (office)

202-577-6657 (cell)

ray@croplife.us

Carmen Tiu has prepared the attached agenda (with minor edits by me). Because of several visitors at different times, we will need to stick quite close to the schedule. Note at the top of the agenda there are two conference call numbers: this first is for our joint lunch session with the Registration Committee, and the next is for the remainder of the meeting.

Also attached are a couple of related documents for discussion during the meeting.

View attachments on the web

Posted by: Ray McAllister <RMcAllister@croplifeamerica.org>

.

To: Housenger, Jack[Housenger.Jack@epa.gov]
From: Kunickis, Sheryl - OSEC
Sent: Wed 11/30/2016 1:52:32 PM
Subject: Chlorpyrifos update to the court

Hi Jack,
I read in the news that you (EPA) are required to provide the court an update by today. Can you share with me what you tell the court? Otherwise, I will just read it in the press.
Hope your Thanksgiving was nice. I took off a week and it was nice to be out of the fray.
Cheers,
Sheryl

Sent from my iPad

To: Housenger, Jack[Housenger.Jack@epa.gov]
Cc: McKalip, Doug - OSEC[Doug.McKalip@osec.usda.gov]
From: Kunickis, Sheryl - OSEC
Sent: Wed 4/20/2016 4:02:26 PM
Subject: Revised comments
2016 Chlorpyrifos SAP - USDA Oral Comments -4-20-16.docx
ATT00001.txt

Hi Jack,
Attached are revised comments. I will provide hard copies after the meeting
Cheers,
Sheryl

To: Housenger, Jack[Housenger.Jack@epa.gov]
From: Kunickis, Sheryl - OSEC
Sent: Fri 4/15/2016 2:24:55 PM
Subject: RE: Organophosphate story
removed.txt

Already got an email and a phone call… ☺ Totally expected. Thanks for the heads up. We are in for an interesting time. You can define interesting… LOL.

From: Housenger, Jack [mailto:Housenger.Jack@epa.gov]
Sent: Friday, April 15, 2016 10:13 AM
To: Kunickis, Sheryl - OSEC
Subject: RE: Organophosphate story

Heads up to you

I told Jim that you were commenting at the sap

He called Melinda Sepp??? To say that was fine if limited to the importance of chlorpyrifos but not the science, other issues

So she may contact you

Just wanted you to know

She did she knew about it and had asked for an outline of your comments so it was not a surprise to her

From: Kunickis, Sheryl - OSEC [mailto:Sheryl.Kunickis@osec.usda.gov]
Sent: Friday, April 15, 2016 8:51 AM
To: Housenger, Jack <Housenger.Jack@epa.gov>
Subject: FW: Organophosphate story

Hi Jack,

The story is linked below. Good to talk with you. Have a good weekend and take the battery out of your phone! It makes life a little more peaceful…. ☺

Story previewing next week's SAP meeting that was published this morning. Here is a link to the story: http://www.bna.com/industry-epa-odds-n57982069835/

Industry, EPA at Odds Over Pesticide Science

www.bna.com

In recent months, the pesticide industry has been advancing a series of arguments calling into question a significant shift in how the Environmental Protection Agency assesses the health risks of...

To: Kunickis, Sheryl - OSEC[Sheryl.Kunickis@osec.usda.gov]
From: Housenger, Jack
Sent: Fri 4/15/2016 2:36:38 PM
Subject: RE: Organophosphate story

I define it by something appropriate to type here

From: Kunickis, Sheryl - OSEC [mailto:Sheryl.Kunickis@osec.usda.gov]
Sent: Friday, April 15, 2016 10:25 AM
To: Housenger, Jack <Housenger.Jack@epa.gov>
Subject: RE: Organophosphate story

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In recent months, the pesticide industry has been advancing a series of arguments calling into question a significant shift in how the Environmental Protection Agency assesses the health risks of...

To: Kunickis, Sheryl - OSEC[Sheryl.Kunickis@osec.usda.gov]
From: Housenger, Jack
Sent: Fri 4/15/2016 2:13:22 PM
Subject: RE: Organophosphate story

Heads up to you

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He called Melinda Sepp??? To say that was fine if limited to the importance of chlorpyrifos but not the science, other issues

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	Industry, EPA at Odds Over Pesticide Science www.bna.com In recent months, the pesticide industry has been advancing a series of arguments calling into question a significant shift in how the Environmental Protection Agency assesses the health risks of...

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To: Kunickis, Sheryl - OSEC[Sheryl.Kunickis@osec.usda.gov]
From: Housenger, Jack
Sent: Wed 11/30/2016 1:55:25 PM
Subject: RE: Chlorpyrifos update to the court

Wasn't aware
Guess I was going to read it there as well
I'll check

-----Original Message-----
From: Kunickis, Sheryl - OSEC [mailto:Sheryl.Kunickis@osec.usda.gov]
Sent: Wednesday, November 30, 2016 8:53 AM
To: Housenger, Jack <Housenger.Jack@epa.gov>
Subject: Chlorpyrifos update to the court

Hi Jack,
I read in the news that you (EPA) are required to provide the court an update by today. Can you share with me what you tell the court? Otherwise, I will just read it in the press.
Hope your Thanksgiving was nice. I took off a week and it was nice to be out of the fray.
Cheers,
Sheryl

Sent from my iPad

To: Jones, Jim[Jones.Jim@epa.gov]
Cc: Cep, Melinda -OSEC[Melinda.Cep@osec.usda.gov]
From: McKalip, Doug - OSEC
Sent: Wed 4/20/2016 2:09:26 PM
Subject: RE: Comments for tomorrow's SAP
2016 Chlorpyrifos SAP - USDA Oral Comments -4-20-16.docx

;;;
Jim,

Thanks for the call this morning. I again apologize that the process we discussed in terms of an early draft exchange didn't take place on this.

I have reworked the statement and have sent the following cleared version to Sheryl for her use. Please let me know if you would like to jump on the phone to discuss. At my desk until 10:30 and then after 11:30.

Beyond the SAP meeting this week, we would like to have discussions with your team to get into some of the technical details on this.

Many thanks,

-Doug

Doug McKalip

Senior Advisor to the Secretary

U.S. Department of Agriculture

(202) 720-3631

Good Morning. Mr. Chairman, members of the Science Advisory Panel, Mr. Housenger, and my other EPA colleagues, thank you for the opportunity to provide comments. My name is Sheryl Kunickis and I am the Director of the U.S. Department of Agriculture – Office of Pest Management Policy.

Ensuring that all parts of U.S. agriculture have the crop protection tools necessary to produce a robust food supply is part of our mission at USDA. The recommendations you will make as part of this Scientific Advisory Panel will have an enormous impact on the world's food supply. The shift EPA is suggesting – from an established point of departure based on acetylcholinesterase inhibition to a new point of departure based on the Columbia University epidemiological study – is momentous and cannot be understated. We at USDA feel very strongly that this type of major change should only be made if the level of confidence – in both the results of the Columbia Study and EPA's approach for using these results – is very high indeed.

Your recommendation for how EPA regulates chlorpyrifos will reach far beyond this one active ingredient, and will affect not only how other organophosphates are regulated, but many other broad classes of pesticides as well. This is a major shift in pesticide regulation, and there are major potential impacts – the cost to our food supply, to our economy, to tax payers, and to low-income Americans.

We at USDA stand ready to have further dialogue and assist in the technical details of this issue. In particular, we believe further interagency discussion regarding the capabilities and limitations of the Columbia University study and of epidemiological studies in general would be a useful dialogue. In addition, we believe additional discussion is warranted regarding the limitations of assessing a single chemical in light of exposure to many different chemicals over a developmentally crucial multi-year period.

For over 40 years, the EPA Office of Pesticide Programs has been the "gold standard" across the world for entities that register and have oversight of pesticides. Because of EPA's scientifically based, well vetted, and transparent approach, the agricultural community has had the confidence to use pesticides as part of a world class agricultural production system. Chlorpyrifos is up first and the subject of this meeting, so let me share the following noting it is but an example of the value of pesticides in general.

Chlorpyrifos is a key tool for farmers in managing a wide array of pest insects and is a critical part of Integrated Pest Management (IPM) programs in well over 50 crops grown throughout the United States. This is due to its efficacy, broad-spectrum activity against multiple pests, and its fit with conservation biological control in crops such as citrus, tree fruit, and cotton. Changes to the process that result in losses of important crop protectants will likely have a significant negative impact on the production capabilities and economic stability of producers of many human and animal food crops. This is true particularly where few or no efficacious insecticide alternatives are available, where resistance management with limited alternatives is a concern, where Maximum Residue Limits (MRLs) for effective insecticide alternatives are not established for export markets, and where crops experience invasive and/or endemic pest outbreaks.

As I said at the beginning, the implications for the outcome on this question are profound – with potential costs to our food supply, to our economy, to tax payers, and to low-income Americans. We would like to work with you further to ensure the very best science-based policy outcome.

Thank you.

To: Jones, Jim[Jones.Jim@epa.gov]
Cc: Milhouse, Gloria[Milhouse.Gloria@epa.gov]
From: Provost, Megan (J)
Sent: Tue 8/23/2016 10:43:30 PM
Subject: Meet with Dow AgroSciences CEO

Hi, Jim. We haven't had a chance to meet in-person yet. I recently took over federal affairs at Dow AgroSciences for Constance Cullman. (I'm assuming you had heard, but If not, Constance left us in June to be the new CEO at the Farm Foundation.)

Our President and CEO, Tim Hassinger, will be in Washington, DC, in September for some meetings, and wanted to see if it would be possible to meet with you while he's in town to discuss some of our products (Enlist, sulfoxaflor, and chlorpyrifos). Would you be available to meet on Tuesday, September 20th?

Many thanks,
Megan

Megan J. Provost
U.S. Government Affairs
Dow AgroSciences
Mobile: (202) 573-3393
Email: mprovost@dow.com

To: Keigwin, Richard[Keigwin.Richard@epa.gov]; Bennett, Tate[Bennett.Tate@epa.gov]; Kaiser, Sven-Erik[Kaiser.Sven-Erik@epa.gov]
Cc: Williams, Jessie (Agriculture)[Jessie_Williams@ag.senate.gov]
From: Swee, Alexandra (Agriculture)
Sent: Thur 5/18/2017 8:34:53 PM
Subject: Transcript edits - 5/11 Hearing
Keigwin_pagesfrom5.11.17AG.pdf

Hi Mr. Keigwin,

Attached are your transcript pages from the 5/11 hearing. Please read over the testimony or remarks and make any necessary edits.

Please make only those edits that are necessary to correct typographical errors and sentence structure or simple changes that clarify your response. The edits cannot change the meaning of statements made during the hearing. If you need to submit an additional comment to correct a factual error, then please submit a statement as an addendum to the original testimony. This will be included in the record along with the original testimony.

The deadline for edits is 5:00 PM on Friday, May 26, 2017. If we do not receive your edits by this date, the testimony will be submitted for the official record as it stands in this document.

To make any edits - print out the PDF document, handwrite the edits, scan and send back the edited pages to Jessie Williams (Jessie_Williams@ag.senate.gov) and Alexandra Swee (Alexandra_Swee@ag.senate.gov).

Thank you,

Ali

ALI SWEE

Staff Assistant/Legislative Correspondent

U.S. Senate Agriculture, Nutrition, and Forestry Committee

Chairman Pat Roberts (R-KS)

328A Russell Senate Office Building

Washington, DC 20510

Main: 202.224.2035

STATEMENT OF RICHARD P. KEIGWIN JR., ACTING DIRECTOR, OFFICE OF PESTICIDE PROGRAMS, U.S. ENVIRONMENTAL PROTECTION AGENCY

Mr. Keigwin. Thank you, Chairman Roberts. Good morning. It is very nice to be here. Chairman Roberts, Ranking Member Stabenow, and members of the Committee, my name is Rick Keigwin, and I currently serve as the acting director of the Office of Pesticide Programs at EPA.

Safe pesticide use makes an enormous contribution to our society, particularly in the production of U.S. food and fiber. Innovation in pesticide use has greatly increased U.S. agricultural productivity and contributed to a predictable food supply and stable food prices.

There are now more than 17,000 registered pesticide products containing more than 1,200 active ingredients, with uses ranging from insect repellents, household cleaners, lawn and garden chemicals, hospital disinfectants, biotechnology products, and a wide range of agricultural chemicals used to provide an abundant food supply.

Working with stakeholders, EPA has developed a highly regarded program for evaluating pesticide safety and making regulatory decisions. Our approach to decision-making is based on a model of transparency. Using this approach, the agency makes decisions consistent with the information that is peer-reviewed and protective of human health and the environment.

Under the Federal Insecticide, Fungicide, and Rodenticide Act, or FIFRA, EPA ensures that when used properly, pesticides provide significant benefits to society, such as controlling disease-causing organisms, protecting the environment from invasive species, and fostering an affordable, safe, and abundant food supply. FIFRA's safety standard requires EPA to weigh these benefits against harm to human health and the environment that might result from using the pesticide.

In addition, under the Federal Food, Drug, and Cosmetic Act, EPA sets tolerances or maximum residue limits for pesticides used on food and animal feed. The EPA may establish a tolerance for a pesticide in food or feed only if we find that there is a reasonable certainty of no harm from exposure, from consumption of the food treated with that pesticide, and from other non-occupational sources.

The Pesticide Registration Improvement Act, or PRIA, as you mentioned, was first signed into law in 2004, and we are now talking about PRIA 4, the third reauthorization of PRIA.

PRIA is a successful example of user fees paid by the private sector supporting vital regulatory programs. EPA's pesticide activities are funded by a combination of appropriations and user fees, with one-time registration service fees accompanying registration applications and annual maintenance fees supporting continued registration of pesticide products.

Under PRIA, entities seeking EPA's approval to sell or distribute pesticide products, in most cases, pay a fee to process their applications. The amount of the fee depends on the type of application, the complexity of the application, and the type of entity. So, for example, a small business pays reduced fees, and Government and Government-sponsored organizations are exempt from paying the PRIA fees.

PRIA was developed by a coalition of pesticide stakeholders representing seven different trade groups within the pesticide industry and public interest groups representing both the farmworker and environmental communities. The result of this collaboration is that there are elements in PRIA that are important to all of the represented stakeholders in the coalition, and EPA for the past many years has served in an advisory capacity to this coalition and has welcomed the opportunity to provide technical assistance to them.

Before PRIA, EPA could not process all of the applications we received in a timely manner. Backlogs developed, and applicants could not predict when the agency could make a decision. With the additional resources provided by PRIA, the agency can now process new applications in a timelier manner. As part of our efforts to continue to improve the registration process, EPA has integrated efficiencies throughout our review process, enabling the agency to successfully meet the requirements of PRIA. Since PRIA became law, the agency has seen an increase in the approval of pesticides for us in growing specialty groups, helping farmers meet their pest control needs.

Further, some of these fees support improved pesticide safety education that helps protect our farmworkers and farmworker families.

In conclusion, the EPA has a history of working in strong collaboration with the grower community to address potential pesticide risks, while providing growers with the necessary tools to meet their pest management needs. Through meetings with growers and agricultural stakeholders, we gain a better understanding of how farmers use these tools to grow their crops.

Thank you for the opportunity to testify today. I will be happy to answer any of your questions. Thank you.

[The prepared statement of Mr. Keigwin follows:]

Chairman Roberts. Thank you so much.

Senator Stabenow, we have two witnesses that were very succinct and on time. I think that is--I am not sure if that is a record, but at any rate--

Senator Stabenow. It may be.

Chairman Roberts. We thank you very much.

Mr. Keigwin, in the context of PRIA, oftentimes the conversation focuses only on the benefits for the registrants. Would you elaborate, please, on the other types of benefits that PRIA provides? And I am going to mention certainty and obviously worker protection.

Mr. Keigwin. Thank you, Senator.

So certainty for growers, I think, is very important. Knowing that tools that are in the pipeline will become available by a date certain, I think it is critically important to help growers meet their pest management needs. EPA has been very successful as part of implementing PRIA that nearly 98 percent of the time or even more frequently, we are meeting the statutory due dates for completing our registration decisions, and that is something that we are very proud of.

PRIA also extends funding for pesticide safety education programs, which is also very critical to ensure that the people that help us grow our food remain safe and that their families remain safe, and the funds from PRIA help to support programs either at land-grant universities or in other organizations to ensure that they have the protections that they need.

One of the new things with PRIA 4 that I would like to highlight is that it sparks innovation for the development of lower-risk pesticides. One of the provisions of PRIA establishes higher fees and longer review times for those products that do not get classified as a reduced-risk or lower-risk pesticide, so the result being that something that does have the merits of being a lower-risk pesticide can be advanced to the market more quickly.

So those would be three that I would highlight for you today.

Chairman Roberts. I appreciate that very much.

Doctor, as the Department of Agriculture--well, number one, you went from North Carolina State to BYU. That is a long ways.

Ms. Kunickis. I went in the other direction. I started out at BYU and ended at North Carolina State.

Chairman Roberts. I see. You just reversed. So instead of going West, young lady, you went East.

Ms. Kunickis. Yes, sir.

Chairman Roberts. All right. Is BYU, the--are they still the Cougars?

Ms. Kunickis. Yes, sir.

Chairman Roberts. I appreciate your response very much.

Senator Stabenow.

Senator Stabenow. Thank you, Mr. Chairman, and thank you to both of our witnesses.

Mr. Keigwin, I first want to thank you personally for your engagement with Michigan State University and our Michigan hop growers that created the gift that we just gave to the Chairman to facilitate Section 18 exemptions under FIFRA.

Most recently, I have heard from Michigan sugar beet growers about emergency use needs under Section 18 as well. What steps can be taken by growers, states, manufacturers, and the EPA to make the Section 18 process more efficient, so that growers facing unexpected risk can get needed crop insurance tools in a timely fashion?

Mr. Keigwin. Thank you, Senator, and I have had the great fortune of meeting with Michigan growers on a number of occasions. Your growers sponsor an annual tour to help educate EPA employees about Michigan agriculture and what farmers do to help grow our crops, so thank you for that.

In terms of Section 18s, we have a pretty solid record of completing our decision-making for most Section 18 or emergency exemptions in less than 50 days, but there are times--and I think this situation with the sugar beet one, growers, that came to your attention highlights the need for early engagement between EPA and the Michigan Department of Agriculture and the grower community and the land-grant universities.

Knowing early on what tools a grower might need to address the emerging pest situation, it is hard when at the end of the process or right when they need to apply the product for EPA to say, "Wait. Hold on. We might have a problem." So one process efficiency would probably be for us to have earlier engagement, maybe even before the state submits their Section 18 request to see if there might be any issues with that particular chemical, and to the extent to which there are, we could work collaboratively with cooperative extension and with the state to maybe find some alternatives that we could move through the process more quickly to address the emerging pest management need.

Senator Stabenow. Thank you very much.

Dr. Kunickis, when developing new integrated pest management strategies with growers, does the USDA staff recommend Farm Bill conservation programs to farmers as a tool to combat weed resistance, and secondly, do you have recommendations for how the conservation programs can be improved to help address weed resistance as well as the continued decline in the pollinator populations?

Ms. Kunickis. Thank you for your question.

Ms. Kunickis. Thank you.

Senator Stabenow. --that you would have on conservation programs.

Mr. Keigwin, can you talk about the role of the EPA's Board of Scientific Counselors in reviewing the safety of crop protection materials?

Mr. Keigwin. For pesticide products and pesticide science, our studies and our methodologies for how we conduct our reviews have not been reviewed by the panel that you referred to. In fact, under FIFRA, there is a separate congressionally chartered peer review body called the FIFRA Scientific Advisory Panel, and so our work is peer-reviewed separately, not through the BOSC, but through the FIFRA SAP.

Senator Stabenow. Thank you very much.

Thank you, Mr. Chairman.

Chairman Roberts. Senator Ernst.

Senator Ernst. Thank you, Mr. Chair, and thanks to our witnesses for being here today. I appreciate it.

Mr. Keigwin, in your testimony, you highlighted the fact that your agency has met the time frame for approval 98 percent of the time on the more than 20,000 decisions since PRIA was enacted in 2004, and I think that is a pretty tremendous track record. And I know there had been some extensions of timelines beyond the target of 730 days but still a very good percentage, so thank you for that.

But what I would like to know is what you believe can be done to remove duplicative regulations, free up some of those funds, or take other actions to further improve the time for getting new products on the market, so we can make our farmers and growers even more productive.

Mr. Keigwin. Thank you, Senator.

When Administrator Pruitt joined the agency, one of the things that he launched straight away was his Back-to-Basics Agenda, which is an initiative to help focus EPA's efforts on returning to our core mission of protecting human health and the environment.

As part of that effort, we have been beginning to reach out to stakeholders across the spectrum to identify areas of regulation that either may be duplicative, could be streamlined or modified, while still protecting public health and the environment.

In fact, last week, the Pesticide Program hosted a public meeting of a wide variety of stakeholders. Several hundred people participated in that meeting to help provide some insight to us on where we might look next in terms of streamlining, gain some additional efficiencies in our program, and among those were opportunities to look at some MOUs with other agencies where there might be opportunities to share our work and share our load or rely upon the work of another agency. So those are among the things that we are beginning to explore now.

Senator Ernst. Very good. And, in your opinion, does that seem to be a positive start? Is it being received well by your agency and other agencies?

Mr. Keigwin. It has, and, in fact, we have had some MOUs in place with other agencies. So this would not be a new territory to explore, but we can build upon some of our existing relationships and probably go further.

Senator Ernst. Very good. Thank you, Mr. Keigwin.

And, Dr. Kunickis, you noted in your testimony that agriculture depends on a strong scientifically based EPA to evaluate pesticides, and what can you do in your role to encourage that and ensure that politics--of course, politics, in the news all the time--that politics do not get in the way of sound science when it comes to reviewing pesticides?

Ms. Kunickis. Thank you. I appreciate that question. Science is the foundation of everything that we do at USDA, and I expect that that is the same for EPA.

For us, we look at what any kind of rules or proposed rules or risk assessments that EPA does, and we look at it through the view of our agricultural sectors to see if it is--how it would work. And then we also look at models, the inputs, to see if they are valid, and if they are reflective of agriculture. But we also look at the science that is this program.

One of the missions of USDA's Office of Pest Management Policy is to promote the development of new pest management approaches that meet the needs of our evolving agriculture industry.

Mr. Keigwin, would EPA be able to examine the numerous pesticide products intended for sale in the U.S. without the resources that PRIA provides? It is called an easy question.

Mr. Keigwin. Thank you, Senator.

[Laughter.]

Mr. Keigwin. We certainly want to be able to do them on the time frames that we do the--the supplemental resources that PRIA provides certainly help us achieve the timelines that I was talking about earlier in my testimony.

Senator Klobuchar. Okay. And to get on to that timelines, I have heard from Minnesota businesses about the importance of having a more predictable timeline during the registration review process. What work have you done to make the regulatory approval process more predictable for industries and producers and the public?

Mr. Keigwin. So an important component of the registration review process is transparency and public engagement, and so we do have multiple opportunities throughout the review process for them to engage, for them to come forward to us with information, so that we are using real-world information in making our decisions, so that we are making the most informed decisions that we can.

Senator Klobuchar. Okay.

Dr. Kunickis, your name is almost as hard as mine. Kunickis. What have you heard from farmers about the need for a timely review, and how does your team at USDA work with EPA?

Ms. Kunickis. We hear a lot from farmers, and actually, we reach out to a lot of the grower groups, folks that we know across the country, to talk to them about their needs.

We work very closely with EPA. We have a great working relationship. I keep in contact regularly with Rick right now on a regular basis. I always ask about what is the status of this pesticide that is in registration review, are there any concerns, are there any data that you need from USDA that we can provide to help inform some of the decisions that you are going to make, and we are very interested in if there is any mitigation measures that may be needed so that we can look and see if they are realistic for our growers.

This afternoon, my staff and I will be at EPA. We have our regular monthly meeting where we have a number of items on an agenda to discuss. So we work really well together, Senator Klobuchar. Mr. Keigwin, in your testimony, you mention that the reauthorization bill passed by the House would increase the types of registration actions covered under PRIA to 212 categories, up from 189 categories in the last reauthorization. Would the fee increase from $27.8 million to $31 million per year cover the additional 23 categories proposed for registration, and do you see the demand outpacing the additional increases for maintenance fees?

Mr. Keigwin. So thank you, Senator. The maintenance fees actually primarily go to fund the reevaluation program. The additional categories will have their own new PRIA fees associated with them, so they will diverge in those two different directions.

Senator Klobuchar. Okay. I see. But the question was, Do you think that fee increase--the initial question--would cover the additional 23 categories? So you think it would?

Mr. Keigwin. So the fee increase is on the maintenance fee side, primarily, so that is for the reevaluation program.

Senator Klobuchar. Okay.

Mr. Keigwin. The 23 new categories will have their own PRIA fees, and then there are fees--there is an increase in some of the fee categories for the new registration side.

So the 23 categories are new registration categories. The fee increase, I think that--I believe you are referring to happens to deal with the maintenance fee side to fund the reevaluation program.

Senator Klobuchar. So you think it is all--

Mr. Keigwin. I think it will certainly help us get the work done.

Senator Klobuchar. So it is all going to be paid for? It will not--okay. All right.

Mr. Keigwin. Coupled with appropriated dollars. We cannot fully fund the--we cannot fully do the work--

Senator Klobuchar. But if you get the 30 percent decrease in the proposed budget that you are supposed to at EPA, would you be able to do all your work?

Mr. Keigwin. You know, as Sheryl said, we would have to figure out how to do things and look for additional efficiencies.

Senator Klobuchar. Okay.

Chairman Roberts. Senator Perdue.

Senator Perdue. I yield, Mr. Chairman.

Chairman Roberts. We have a Perdue that is not talking. That is very unusual.

[Laughter.]

Senator Klobuchar. He is trying to be nice to the other members.

necessary or moving in that direction to protect human health. Can you comment on that?

Mr. Keigwin. Sure. Thank you, Senator.

So we have been studying chlorpyrifos for quite some time and took regulatory action to mitigate some of the exposures to chlorpyrifos back in the last decade when we removed it from uses around the--most uses around the home, and about four or five--

Senator Van Hollen. The indoor, the indoor use.

Mr. Keigwin. The indoor uses, like the termiticide type of uses.

We also worked very successfully with the registrants about four or five years ago to put in place some buffers to protect residential areas around agricultural fields to deal with some spray drift issues.

I think what you are referring to, Senator, is a rulemaking that we were in the midst of that we began in 2015 when we proposed to revoke the tolerances for chlorpyrifos, because the science that we had at the time suggested that we potentially could not make the required safety finding under the Food, Drug, and Cosmetic Act.

We continue to do our work, and we took a revised assessment to our FIFRA Scientific Advisory Panel in the spring of 2016. They recommended some improvements to that risk assessment, and so in November of 2016, we issued a revised draft risk assessment for public comment, and that public comment period closed in mid-January.

We received almost 50,000 comments on that draft risk assessment, and a number of those comments raised some questions about how EPA had done the science, had concerns about how we had derived the regulatory endpoint from an epidemiology study, and strongly urged the agency to have that risk assessment further peer-reviewed before we completed regulatory action.

The decision that the Administrator made at the end of March was--while related to the rulemaking, was in response to a petition from the Pesticide Action Network of North America and the Natural Resources Defense Council. That action is now in litigation, so I have got to be very circumspect about what I say because it is an active litigation. But, in the meantime, we are continuing to review the science surrounding chlorpyrifos, taking into account the comments that we received during the public comment period.

Senator Van Hollen. So the review is ongoing now--

Mr. Keigwin. The review--

Senator Van Hollen. --and has not been stopped?

Mr. Keigwin. The review has not been stopped. It is ongoing as part of the re-registration process.

Senator Van Hollen. All right. Well, Mr. Chairman, I hope we will all adhere to the advice from our colleague, which is this be done based on the science and not the politics. I hope we can all agree with that proposition. We need to, obviously, prevent pests from chewing up our crops, but we also need to protect human health. So I look forward to continuing this conversation with you.

Just if I could ask, Mr. Chairman, have any of our--where are European partners in--are any of them in process of looking at banning this?

Mr. Keigwin. A number of other countries have reevaluations under way. Australia, as an example, just within the last couple of weeks, released a risk assessment for chlorpyrifos. Their risk assessment is different from ours, and so we are looking at the science that the Australian government considered and seeing what parts of that would be appropriate for us to use here.

Chairman Roberts. I thank the Senator.

Senator Perdue.

Senator Perdue. I yield again, Mr. Chairman.

Chairman Roberts. Gracious.

Senator Heitkamp, would you like to proceed at this point?

Senator Heitkamp. Well, I would love to. Thank you, Mr. Chairman, for the gracious offer.

Chairman Roberts. Well, thank you for coming.

produces in the field here for our ag industry. And reauthorizing the Pesticide Registration Improvement Act will be an important step towards reducing some of that uncertainty that exists today.

Pesticides play a vital role for farmers in keeping our pest populations down, improving our yields, certainly reducing the impact of diseases. In fact, in Montana, there is over 6,000 private pesticides applicators, and ensuring they and our producers have access to a safe and effective pesticides in a timely manner is simply imperative.

Dr. Kunickis, one thing I hear frequently from farmers and ranchers in Montana is the burden of duplicative or unduly burdensome regulations. In your testimony, you state that the EPA is required to review the impact of pesticides under the Endangered Species Act, despite the EPA already being required to review the pesticides to avoid, and I quote, "any unreasonable risk to man or the environment," end quote, under FIFRA. Would you view this as an example of a duplicative regulation?

Ms. Kunickis. Yes, sir, I would.

Senator Daines. Mr. Keigwin, on a similar note, does using ESA to regulate pesticides pose any challenges for your office and the EPA more broadly?

Mr. Keigwin. ESA consultations and the assessment processes are new for us. We have been working with the

Fish and Wildlife Service and the National Marine Fisheries Service to develop sound scientific procedures for how to evaluate the effects of pesticides on endangered and threatened species, and with the assistance of the National Academy of Sciences, they did give us some advice a few years ago about how to do that. But it is a much more complex evaluation process than what we have traditionally done for pesticides under FIFRA.

Senator Daines. Thank you.

Dr. Kunickis, I do not have a lot of claim to fame, other than I am the husband of Cindy Daines, but I am the only chemical engineer on the Hill amongst 535 members. And that is what my training was in. I do understand the importance of utilizing sound science in our decision-making processes, and as you well know, there was an extended and vigorous debate surrounding the mandatory labeling of biotechnology last year.

And I got to thank Chairman Roberts and his leadership. We were successfully able to prevent what I believe was a discriminatory and harmful law from impacting our farmers across Montana and across the country.

As you know, the Office of Pest Management Policy plays an important role in developing and implementing biotech policy at USDA in collaborating with EPA. As you work to develop and implement rules related to biotech disclosure in advance of next year's deadline, will you commit to ensuring that USDA's priority will be to make determinations based on sound science?

Ms. Kunickis. Absolutely.

Senator Daines. Thank you for that. I have found in this town that political science sometimes becomes the primary message, and I want to always come back to the sound science and the facts. USDA has to be focused on the safety of the food and products with its jurisdiction, not on marketing and mandatory labeling efforts that have no bearing on food safety or plant pest risk.

Mr. Keigwin, what would be the implications the average farmer or producer in Montana if PRIA were not reauthorized?

Mr. Keigwin. One of the advantages of PRIA is that it does give growers some certainty about the availability of when new products will become tools for them.

In the absence of PRIA, if you go back to what the regulatory atmosphere was like prior to PRIA--I will give an example that a grower shared with me just yesterday. A new active ingredient before PRIA took about six years for EPA to complete the review for. Now it takes about two years, so the review process has been shaved rather significantly, while still ensuring that that registration is protective of human health and the environment.

Senator Daines. Mr. Keigwin, last question. As you know, there were instances in the past Administration where concerns were raised regarding the consultation of communication between EPA and USDA. What steps does your office take to consult with the Office of Pest Management or other agencies within USDA?

Mr. Keigwin. So Sheryl and I talk regularly. This is not just the first time today that we will be talking. We have a meeting this afternoon. We get together at least on a monthly basis.

Senator Daines. So do you even need two offices? Is that what you are saying? You could--

Mr. Keigwin. I am not saying that.

[Laughter.]

Mr. Keigwin. But our staffs are well integrated. She has some former staff of mine.

I would like to get some of them back, Sheryl.

But it is a very good working relationship, and while we do not always agree, we find a way to work through the issue in a collaborative manner.

Senator Daines. All right. Thank you.

Chairman Roberts. Senator Gillibrand.

Senator Gillibrand. Thank you, Mr. Chairman, and thank you to both of you for your service.

Dr. Kunickis, in your testimony, you stated that it is extremely important to the USDA that agriculture not be

Administrator Pruitt's Back-to-Basics Agenda and how he is committed to returning common sense as well as transparent and peer-reviewed science to pesticide registration process. You have been in EPA leadership for more than 20 years. During that time, have EPA scientists ever done anything less than their very best to conduct rigorous analysis of the risks posed by pesticides to farmers and consumers?

Mr. Keigwin. Our scientists are among the most highly regarded scientists on pesticide regulation, and they do routinely seek peer review of their work.

Senator Gillibrand. And do you believe that Administrator Pruitt's recent dismissal of as many as half the scientists of the Board of Science Counselors in favor of industry representatives was done to improve science?

Mr. Keigwin. Senator, I cannot respond to that in that the work that my office does is peer-reviewed by a different panel, the FIFRA Scientific Advisory Panel, which is a congressionally chartered peer review committee, and there has not been any change to the scientific makeup of that committee.

Senator Gillibrand. You mentioned in your testimony that Pesticide Registration Improvement Act fees cover about 20 to 40 percent of EPA's total review cost. The President's budget would cut EPA funding by 31 percent and eliminate pesticide safety programs. With such deep cuts, would there be any way that EPA could conduct accurate and timely reviews of submissions?

Mr. Keigwin. So I have not seen what the President will ultimately propose. Obviously, a reduction in our congressional appropriations would have an impact on the program.

Senator Gillibrand. How high would PRIA fees need to be if these cuts happened?

Mr. Keigwin. So PRIA fees right now cover about 30 to 35 percent of the program costs. So a reduction would--potentially would necessitate, if that were an issue on the table, for a higher fee. There is also opportunities for us to look at further efficiencies in our process so that we could absorb some of the resources.

Senator Gillibrand. And how would you--how would proposed budget cuts affect research and integrated pest management?

Mr. Keigwin. So EPA does not conduct research on integrated pest management. That is something that we rely upon our partners at USDA to do.

Senator Gillibrand. Thank you, Mr. Chairman.

Chairman Roberts. Senator Boozman.

Senator Boozman. Thank you, Mr. Chairman, and thank you all for holding this hearing. It really is very, very important.

I do not have any doubt that you all work together well, and that is a good thing. You mentioned that sometimes you do not agree. Who has got final authority, or do you just kind of not do anything when you run into--

Mr. Keigwin. In the ideal world, we find ways to reach agreement, and we do that many, many times.

Senator Boozman. But we do not live in an idea world.

Mr. Keigwin. But I think the relationship that the Office of Pesticide Programs and the Office of Pesticide Management Policy has been such that we successfully work through our areas of disagreement, and I think it is very rare when there is true disagreement. Sometimes it is just a nuance or a different way of looking at an issue, and I think I am very proud of the fact that we have been able to work well together to put in place the necessary protections for pesticides where they are needed and ensure that growers have the tools that they need to produce their crops.

Senator Boozman. No, and that is--again, that is appreciated.

Dr. Kunickis, when I am home, traveling about Arkansas, like most of our states, it is such a heavily agricultural state. It does not really matter what state it is. It is remarkable, the percentage of GDP that our states have.

But I really feel very strongly that the answers to our problems really do need to come from the ground up. Can you little faster than the regulatory process.

Senator Thune. Right.

Do you have anything to add, Mr. Keigwin?

Mr. Keigwin. Senator Thune, I think the other thing that I would add to what Sheryl just mentioned is that over the past couple of years, USDA, EPA, working with our colleagues at the Food and Drug Administration, have been going through a systematic process of updating the system that we use to regulate products and biotechnology.

To specifically address the point that you were making about new products coming through the pipeline, the three agencies worked together and commissioned a review by the National Academy of Sciences to give us some insight on what new tools were coming down the pike, so that, in fact, we could be better prepared to make regulatory decisions to enable those products to come onto the market as quickly as they can.

Senator Thune. Yeah. And I agree. I mean, you cannot keep up with sometimes what is happening out there, but we have to do the best we can, and there are lots of wonderful things that are happening in technology that will make us more efficient and more productive.

So I represent South Dakota, and we are one of the top honey-producing states in the nation, and so I wonder if you could tell me if any progress is being made to combat the

Varroa mite, which is something that contributes to what we call CCD or Colony Collapse Disorder, something that has really affected the bee population in this country and, as a consequence of that, honey production. Do you have anything on that?

Mr. Keigwin. So one of the things that EPA has done is that when a new tool is even in the discovery process to control Varroa mite, we will accelerate the registration of that product through the process as quickly as possible.

We had an example from just a couple of years ago that there was a tool that was available to Canadian beekeepers that we not available to U.S. beekeepers. Because of the scientific relationships that we have developed with our colleagues in Canada, we were able to make use of their reviews. And this was a new active ingredient for us, and we were able to complete the registration process for that product in four months because of our ability to rely upon the science that our colleagues in Canada had already undertaken.

Senator Thune. Well, it is a huge problem. CCD has just destroyed beehives all across the country, and the losses that our bee producers are incurring continue to mount and to pile up. And so much of this is just doing this research and trying to find solutions. So I hope you will keep up, keep up with that, and the folks out there who